91-02P

SOCIAL SECURITY ADMINISTRATION

20 CFR Parts 404 and 416

[Docket No. SSA-2017-0042]

RIN 0960-AG65

Revised Medical Criteria for Evaluating Digestive Disorders and Skin Disorders

AGENCY: Social Security Administration.

ACTION: Final rule.

SUMMARY: We are revising the criteria in the Listing of Impairments (listings) that we use to evaluate claims involving digestive disorders and skin disorders in adults and children under titles II and XVI of the Social Security Act (Act). The revisions reflect our adjudicative experience, advances in medical knowledge, and comments we received from the public in response to a notice of proposed rulemaking (NPRM).

DATES: This rule is effective [INSERT DATE 120 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Michael J. Goldstein, Office of Disability Policy, Social Security Administration, 6401 Security Boulevard, Baltimore, Maryland 21235-6401, (410) 965-1020.

For information on eligibility or filing for benefits, call our national toll-free number, 1-800-772-1213, or TTY 1-800-325-0778, or visit our internet site, Social Security Online, at *http://www.socialsecurity.gov*.

SUPPLEMENTARY INFORMATION:

Background

The listings describe medical conditions that are so severe that we presume any adult who has a medical condition(s) that satisfies the criteria of a listing is unable to

perform any gainful activity regardless of their age, education, or work experience and, therefore, is disabled.[1] For children, the listings describe impairments we consider severe enough to cause marked and severe functional limitations.[2] We use the listings at step 3 of the sequential evaluation process to identify claims that we should clearly allow.[3] We do not deny any claim solely because a person's medical condition(s) does not satisfy the criteria of a listing.

We last published final rules that revised the digestive disorders listings on October 19, 2007, and the skin disorders listings on June 9, 2004.[4] We published an Advance Notice of Proposed Rulemaking (ANPRM) for digestive disorders in the *Federal Register* on December 12, 2007.[5] We published an ANPRM for skin disorders in the *Federal Register* on November 10, 2009.[6]

We are making final the rule for evaluating digestive disorders and skin disorders that we proposed in the NPRM published in the *Federal Register* on July 25, 2019.[7] The preamble to the NPRM provides the background for these revisions. You can view the preamble to the NPRM by visiting *http://www.regulations.gov* and searching for document "SSA-2017-0042." There are differences from the NPRM to this final rule in response to public comments to the NPRM, which we explain below.

Why are we revising the listings for evaluating digestive disorders and skin disorders?

We developed this final rule as part of our ongoing review of the listings. We are revising the listings for evaluating digestive disorders and skin disorders to update their medical criteria, and to clarify how we evaluate digestive disorders and skin disorders.

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[1] 20 CFR 404.1525(a) and 416.925(a).
[2] 20 CFR 416.925(a).
[3] 20 CFR 404.1520, 416.920, and 416.924.
[4] 72 FR 59398 (2007) and 69 FR 32260 (2004).
[5] 72 FR 70527 (2007).
[6] 74 FR 57972 (2009), with the docket number corrected at 74 FR 62518 (2009).
[7] 84 FR 35936 (2019).

When will we begin to use this final rule?

As we noted in the dates section of this preamble, this final rule will be effective on [INSERT DATE 120 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. We delayed the effective date of the rule to give us time to update our systems and to provide training and guidance to all of our adjudicators before we implement the final rule. The current rules will continue to apply until the effective date of the final rule. When the final rule becomes effective, we will apply it to new applications filed on or after the effective date of the rule, and to claims that are pending on or after the effective date.[8]

We present a series of tables below. These tables summarize revisions we made to the digestive disorders and skin disorders introductory text and listings. Following the tables, we discuss the changes in detail.

DIGESTIVE DISORDERS

The following table summarizes the current and revised sections of the adult digestive disorders introductory text and listings:

Sections of the Adult Introductory Text and Listings for the Digestive System Prior to the Effective Date of this Final Rule	**Revised Sections of the Adult Introductory Text and Listings for Digestive Disorders**
Introductory Text, 5.00	
A. What kinds of disorders do we consider in the digestive system?	A. Which digestive disorders do we evaluate in this body system?
B. What documentation do we need?	B. What evidence do we need to evaluate your digestive disorder?
C. How do we consider the effects of treatment?	[5.00 H.]
D. How do we evaluate chronic liver disease?	C. What is chronic liver disease (CLD), and how do we evaluate it under 5.05?

[8] This means that we will use this final rule on and after the effective date in any case in which we make a determination or decision. We expect that Federal courts will review our final decisions using the rules that were in effect at the time we issued the decisions. If a court reverses our final decision and remands a case for further administrative proceedings after the effective date of this final rule, we will apply this final rule to the entire period at issue in the decision we make after the court's remand.

E. How do we evaluate inflammatory bowel disease (IBD)?	D. What is inflammatory bowel disease (IBD), and how do we evaluate it under 5.06?
F. How do we evaluate short bowel syndrome (SBS)?	E. What is intestinal failure and how do we evaluate it under 5.07?
G. How do we evaluate weight loss due to any digestive disorder?	F. How do we evaluate weight loss due to any digestive disorder under 5.08?
[5.00 D.12.]	G. How do we evaluate digestive organ transplantation?
H. What do we mean by the phrase "consider under a disability for 1 year"?	[5.00 C.2. and G.]
[5.00 C.6.]	H. How do we evaluate your digestive disorder if there is no record of ongoing treatment?
	I. How do we evaluate your digestive disorder if there is evidence establishing a substance use disorder?
I. How do we evaluate impairments that do not meet one of the digestive disorder listings?	J. How do we evaluate digestive disorders that do not meet one of these listings?
Listings	
5.01 Category of Impairments, Digestive System	5.01 Category of Impairments, Digestive Disorders
5.02 Gastrointestinal hemorrhaging from any cause, requiring blood transfusion	5.02 Gastrointestinal hemorrhaging from any cause, requiring three blood transfusions
5.03 [Reserved]	5.03 [Reserved]
5.04 [Reserved]	5.04 [Reserved]
5.05 Chronic liver disease (CLD)	5.05 Chronic liver disease (CLD)
5.06 Inflammatory bowel disease (IBD)	5.06 Inflammatory bowel disease (IBD)
5.07 Short bowel syndrome (SBS)	5.07 Intestinal failure
5.08 Weight loss due to any digestive disorder	5.08 Weight loss due to any digestive disorder
5.09 Liver transplantation	5.09 Liver transplantation
	5.10 [Reserved]
	5.11 Small intestine transplantation
	5.12 Pancreas transplantation

The following table summarizes the current and revised sections of the childhood digestive disorders introductory text and listings:

Sections of the Childhood Introductory Text and Listings for the Digestive System Prior to the Effective Date of this Final Rule	**Revised Sections of the Childhood Introductory Text and Listings for Digestive Disorders**
Introductory Text, 105.00	
A. What kinds of disorders do we consider in the digestive system?	A. Which digestive disorders do we evaluate in this body system?

B. What documentation do we need?	B. What evidence do we need to evaluate your digestive disorder?
C. How do we consider the effects of treatment?	[105.00 J.]
D. How do we evaluate chronic liver disease?	C. What is chronic liver disease (CLD), and how do we evaluate it under 105.05?
E. How do we evaluate inflammatory bowel disease (IBD)?	D. What is inflammatory bowel disease (IBD), and how do we evaluate it under 105.06?
F. How do we evaluate short bowel syndrome (SBS)?	E. What is intestinal failure, and how do we evaluate it under 105.07?
G. How do we evaluate growth failure due to any digestive disorder?	F. How do we evaluate growth failure due to any digestive disorder under 105.08?
[105.00 D.13.]	G. How do we evaluate digestive organ transplantation?
H. How do we evaluate the need for supplemental daily enteral feeding via a gastrostomy?	H. How do we evaluate the need for supplemental daily enteral feeding via a gastrostomy, duodenostomy, or jejunostomy?
I. How do we evaluate esophageal stricture or stenosis?	I. How do we evaluate esophageal stricture or stenosis?
J. What do we mean by the phrase "consider under a disability for 1 year"?	[105.00 C.2., C.4., and G.]
[105.00 C.6.]	J. How do we evaluate your digestive disorder if there is no record of ongoing treatment?
	K. How do we evaluate your digestive disorder if there is evidence establishing a substance use disorder?
K. How do we evaluate impairments that do not meet one of the digestive disorder listings?	L. How do we evaluate digestive disorders that do not meet one of these listings?
Listings	
105.01 Category of Impairments, Digestive System	105.01 Category of Impairments, Digestive Disorders
105.02 Gastrointestinal hemorrhaging from any cause, requiring blood transfusion	105.02 Gastrointestinal hemorrhaging from any cause, requiring three blood transfusions
105.03 [Reserved]	105.03 [Reserved]
105.04 [Reserved]	105.04 [Reserved]
105.05 Chronic liver disease	105.05 Chronic liver disease (CLD)
105.06 Inflammatory bowel disease (IBD)	105.06 Inflammatory bowel disease (IBD)
105.07 Short bowel syndrome (SBS)	105.07 Intestinal failure
105.08 Growth failure due to any digestive disorder	105.08 Growth failure due to any digestive disorder
105.09 Liver transplantation	105.09 Liver transplantation
105.10 Need for supplemental daily enteral feeding via a gastrostomy	105.10 Need for supplemental daily enteral feeding via a gastrostomy, duodenostomy, or jejunostomy
	105.11 Small intestine transplantation
	105.12 Pancreas transplantation

The following table shows our changes to the adult and childhood digestive disorders listings criteria that involve changes to healthcare utilization and condition/episode requirements, the rationale for each change, and supporting resources. The table first summarizes the policy changes that apply to multiple adult and childhood digestive disorders listings and then focuses on changes in specific listings.

Adult and Childhood Digestive Disorders Listing Criteria Change in Healthcare Utilization That Applies to Multiple Listings: Change to 12-Month Timeframe in Listing Criteria Requiring Documentation of Findings on Two or More Occasions			
Introductory Text or Listing Criteria Prior to the Effective Date of this Final Rule	Revised Listing Criteria	Rationale	Resources
5.02/105.02 Gastrointestinal hemorrhaging from any cause, requiring blood transfusion (with or without hospitalization) of at least 2 units of blood per transfusion (or at least 10 cc of blood/kg of body weight per transfusion for children), and occurring at least three times during a consecutive 6-month-period. The transfusions must be at least 30 days apart within the 6-month period.	5.02/105.02 Gastrointestinal hemorrhaging from any cause, requiring three blood transfusions of at least 2 units of blood per transfusion, or at least 10 cc of blood/kg of body weight per transfusion, within a consecutive 12-month period and at least 30 days apart.	The revised text is more consistent with our statutory definition of disability; that is, the inability to do any substantial gainful activity by reason of any medically determinable physical or mental impairment which can be expected to result in death or which has lasted or can be expected to last for a continuous period of not less than 12 months.	Section 223(d)(1)(A) of the Social Security Act.

5.05B/105.05B Chronic liver disease, with: Ascites or hydrothorax not attributable to other causes, despite continuing treatment as prescribed, present on at least 2 evaluations at least 60 days apart within a consecutive 6-month period. Each evaluation must be documented by:	5.05B/105.05B Chronic liver disease (CLD) (see 5.00C) with A, B, C, D, E, F, or G: Ascites or hydrothorax not attributable to other causes (see 5.00C2b and 105.00C2b), present on two evaluations within a consecutive 12-month period and at least 60 days apart. Each evaluation must document the ascites or hydrothorax by 1, 2, or 3:		
5.05F/105.05F Chronic liver disease, with: Hepatic encephalopathy as described in 5.00D10, with 1 and either 2 or 3: 1. Documentation of abnormal behavior, cognitive dysfunction, changes in mental status, or altered state of consciousness (for example, confusion, delirium, stupor, or coma), present on at least two evaluations at least 60 days apart within a consecutive 6-month period; 3. One of the following occurring on at least two evaluations at least 60 days apart within the same	5.05F/105.05F Chronic liver disease (CLD) (see 5.00C) with A, B, C, D, E, F, or G: Hepatic encephalopathy (see 5.00C2f and 105.00C2f) with documentation of abnormal behavior, cognitive dysfunction, changes in mental status, or altered state of consciousness (for example, confusion, delirium, stupor, or coma), present on two evaluations within a consecutive 12-month period and at least 60 days apart and either 1 or 2: 2. One of the following on at least two evaluations at		

consecutive 6-month period as in F1:	least 60 days apart within the same consecutive 12-month period as in F:		
5.05G/105.05G End stage liver disease with SSA CLD scores of 22 or greater calculated as described in 5.00D11.	5.05G/105.05G Two SSA CLD scores (see 5.00C3) of at least 20 within a consecutive 12-month period and at least 60 days apart.		
5.06/105.06 Inflammatory bowel disease (IBD) documented by endoscopy, biopsy, appropriate medically acceptable imaging, or operative findings with: A. Obstruction of stenotic areas (not adhesions) in the small intestine or colon with proximal dilatation, confirmed by appropriate medically acceptable imaging or in surgery, requiring hospitalization for intestinal decompression or for surgery, and occurring on at least two occasions at least 60 days apart within a consecutive 6-month period; OR B. Two of the following despite continuing treatment as prescribed and occurring within the	5.06/105.06 Inflammatory bowel disease (IBD) (see 5.00D/105.00D) documented by endoscopy, biopsy, imaging, or operative findings, and demonstrated by A, B, or C: A. Obstruction of stenotic areas (not adhesions) in the small intestine or colon with proximal dilatation, confirmed by imaging or in surgery, requiring two hospitalizations for intestinal decompression or for surgery, within a consecutive 12-month period and at least 60 days apart. OR B. Two of the following occurring within a consecutive 12-month period and at least 60 days apart:		

same consecutive 6-month period:			
5.08 Weight loss due to any digestive disorder despite continuing treatment as prescribed, with body mass index (BMI) of less than 17.50 calculated on at least two evaluations at least 60 days apart within a consecutive 6-month period.	5.08 Weight loss due to any digestive disorder (see 5.00F), despite adherence to prescribed medical treatment, with BMI of less than 17.50 calculated on at least two evaluations at least 60 days apart within a consecutive 12-month period.		

Adult and Childhood Digestive Disorders Listings Criteria – Changes in Healthcare Utilization			
Introductory Text – 5.00/105.00			
Introductory Text or Listing Criteria Prior to the Effective Date of this Final Rule	Revised Introductory Text or Listing Criteria	Rationale	Resources
5.00D/105.00D (How do we evaluate chronic liver disease) 11. End stage liver disease (ESLD) documented by scores from the SSA Chronic Liver Disease (SSA CLD) calculation (5.05G/105.05G1). b. To calculate the SSA CLD score, we use a formula that includes three laboratory values: Serum total bilirubin (mg/dL), serum	5.00/105.00C (What is chronic liver disease (CLD) and how do we evaluate it?) 3. SSA Chronic Liver Disease (SSA CLD) score (5.05G/105.05G[9]). Listing 5.05G requires two SSA CLD scores, each requiring three or four laboratory values. The "date of the SSA CLD score" is the date of the earliest of the three or four laboratory values used for its calculation.	The revised introductory text adds serum sodium, to be considered under certain conditions, in the CLD formula. The Model for End-Stage Liver Disease (MELD) formula, from which the CLD formula is based and is the mathematical equivalent to, was updated in 2016 to add the serum sodium levels. We added serum sodium levels because, for individuals with certain liver conditions such as alcoholic hepatitis and cirrhosis, medical research shows serum sodium levels predict negative outcomes more accurately than formulas without it.	Organ Procurement and Transplantation Network & United Network for Organ Sharing. (2015). Changes to OPTN bylaws and policies from actions at OPTN/UNOS Executive

[9] The childhood digestive disorders listing includes SSA CLD-P scores (see 105.00C3). We are not proposing changes to the SSA CLD-P formula. This table discusses changes to the SSA CLD formula only.

creatinine (mg/dL), and International Normalized Ratio (INR).	The date of the second SSA CLD score must be at least 60 days after the date of the first SSA CLD score and both scores must be within the required 12-month period. If you have the two SSA CLD scores required by 5.05G, we will find that your impairment meets the criteria of the listing from at least the date of the first SSA CLD score. a. We calculate the SSA CLD score using a formula that includes up to four laboratory values: Serum creatinine (mg/dL), total bilirubin (mg/dL), INR, and under certain conditions, serum sodium (mmol/L). The SSA CLD score calculation contains at least one, and sometimes two, parts, as described in (i) and (ii).		Committee meetings July 2015-November 2015 [PDF]. https://optn.transplant.hrsa.gov/media/1575/policynotice_20151101.pdf Vaa, B. E., Asrani, S. K., Dunn, W., Kamath, P. S., & Shah, V. H. (2011). Influence of serum sodium on MELD-based survival prediction in alcoholic hepatitis. Mayo Clinic Proceedings, 86(1), 37-42. Londoño, M.-C., Cárdenas, A.,

			Guevara, M., Quintó, L., de las Heras, D., Navasa, M., Rimola, A., Garcia-Valdecasas, J.-C., Arroya, V., & Ginès, P. (2007). MELD score and serum sodium in the prediction of survival of patients with cirrhosis awaiting liver transplantation. Gut, 56(9), 1283-1290. https://doi.org/10.1136/gut.2006.102764
Listing 5.05/105.05 Chronic Liver Disease (CLD)			
5.05G/105.05G End stage liver disease with SSA CLD scores of 22 or greater calculated as described in 5.00D11.	5.05G/105.05G Two SSA CLD scores (see 5.00C3) of at least 20 within a consecutive 12-month period and at least 60 days apart.	The revised listing reduces the current listing level end stage liver disease CLD score of 22 to 20. Two scores of at least 20 accurately identify advanced, end stage liver disease that prevents a person from working and, without a liver transplant, will ultimately result in death. The unchanged requirement of a second score at least 60 days after the first score is to confirm chronicity, which is critical for confirming continued severity. We have also modified this score for children above the	Annamalai, A., Harada, M., Chen, M., Tran, T., Ko, A., Ley, E., ... Noureddin, M. (2016). Predictors of mortality in the critically ill cirrhotic patient: Is

		age of 12 in the childhood listing (see 105.05G2).	the model for end-stage liver disease enough? Journal of the American College of Surgeons, 224(3), 276-282. https://doi.org/10.1016/j.jamcollsurg.2016.11.005 Zhiang, E., Zhang, Z., Want, S., Xiao, Z., Gu, J., Xiong, M., ... Huang, Z. (2016). Predicting the severity of liver cirrhosis through clinical parameters. Journal of Surgical Research, 204(2), 274-281. https://doi.org/10.1016/j.jss.2016.04.036 Singal, A. K. & Kamath, P. S. (2013). Model for end-stage

			liver disease. Journal of Clinical and Experimental Hepatology, 3(1), 50-60. https://doi.org/10.1016/j.jceh.2012.11.002 Bittermann, T., Makar, G., & Goldberg, D. S. (2015). Early post-transplant survival: Interaction of MELD score and hospitalization status. Journal of Hepatology, 63(3), 601-608. https://www.sciencedirect.com/science/article/pii/S0168827815002445?via%3Dihub
Listing 5.06/105.06 Inflammatory bowel disease (IBD)			
5.06B/105.06B Inflammatory bowel disease (IBD)documented by endoscopy, biopsy, appropriate medically acceptable imaging, or	5.06B/105.06B Inflammatory bowel disease (IBD) (see 5.00D and 105.00D) documented by endoscopy, biopsy, imaging, or operative	The revised listing text removes the requirement that pain not be completely controlled by prescribed narcotic medication. If a person is prescribed any medication, including opioid or other narcotic medication, and	20 CFR 404.1530 and 416.930. Need to follow

operative findings with: Two of the following despite continuing treatment as prescribed and occurring within the same consecutive 6-month period: 3. Clinically documented tender abdominal mass palpable on physical examination with abdominal pain or cramping that is not completely controlled by prescribed narcotic medication, present on at least two evaluations at least 60 days apart; or 4. Perineal disease with a draining abscess or fistula, with pain that is not completely controlled by prescribed narcotic medication, present on at least two evaluations at least 60 days apart; or	findings, and demonstrated by A, B, or C: Two of the following occurring within a consecutive 12-month period and at least 60 days apart: 3. Clinically documented tender abdominal mass palpable on physical examination with abdominal pain or cramping; or 4. Perianal disease with a draining abscess or fistula; or	chooses to not take the medication, we use our rules regarding the need to follow prescribed treatment, which apply to all medical conditions, not just digestive disorders. In subregulatory policy, we also include the "risk of addiction to opioid medication" as an example of a "good cause" reason for not following prescribed treatment." Since it is already our policy that a lack of, or reduction of, opioid or narcotic prescriptions due to the risk of addiction will not adversely affect a person's claim during the adjudication process, we removed consideration of narcotic medication from these listings.	prescribed treatment. SSR 18-3p: Titles II and XVI: Failure to Follow Prescribed Treatment.
5.06B/105.06B Inflammatory bowel disease (IBD)documented by endoscopy, biopsy, appropriate medically acceptable imaging, or operative findings with: 6 (5 for childhood). Need for supplemental daily enteral nutrition	5.06B/105.06B Inflammatory bowel disease (IBD) (see 5.00D and 105.00D) documented by endoscopy, biopsy, imaging, or operative findings, and demonstrated by A, B, or C: 5. Need for supplemental daily	The revised listing expands the alternative method of supplemental daily enteral nutrition to meet the listing to include duodenostomy and jejunostomy. We added these two additional methods of tube feeding after we received public comment requesting that we expand tube feedings to those beyond gastric which are often required in patients with digestive disorders.	Public comment: https://www.regulations.gov/comment/SSA-2017-0042-0008 Pearce, C. B. & Duncan, H. D. (2002).

via a gastrostomy or daily parenteral nutrition via a central venous catheter.	enteral nutrition via a gastrostomy, duodenostomy, or jejunostomy, or daily parenteral nutrition via a central venous catheter.		Enteral feeding. Nasogastric, nasojejunal, percutaneous endoscopic gastrostomy, or jejunostomy: its indications and limitations, Postgraduate Medical Journal, 78, 198-204. https://doi.10.1136/pmj.78.918.198 Brett, K. & Argáez, C. (2018). Gastrostomy versus gastrojejunostomy and/or jejunostomy feeding tubes: a review of clinical effectiveness, cost-effectiveness and guidelines. Ottawa (ON): Canadian Agency for Drugs and Technologi

			es in Health. Clinical Nutrition University. (2021, May 25). *Types of Feeding Tubes EXPLAINED*. YouTube. https://www.youtube.com/watch?v=4Oam1yUHiO8.
No current listing criteria	5.06C Repeated complications of IBD (see 5.00D5a), occurring an average of three times a year, or once every 4 months, each lasting 2 weeks or more, within a consecutive 12-month period, and marked limitation (see 5.00D5c) in one of the following: 1. Activities of daily living (see 5.00D5d); or 2. Maintaining social functioning (see 5.00D5e); or 3. Completing tasks in a timely manner due to deficiencies in concentration, persistence, or pace (see 5.00D5f).	The revised listing combines required medical findings with specific limitations in functioning to identify IBD of listing-level severity. Specifically, the revised listing adds a criterion for repeated complications of IBD that result in marked limitation in at least one area of functioning. This combination of findings accurately characterizes complications of IBD that prevent a person from engaging in any gainful activity. The addition of functional criteria is also consistent with the listings that already include these same functional criteria, which are 7.18 (Repeated complications of hematological disorders), 14.02B (Repeated manifestations of systemic lupus erythematosus), 14.04D (Repeated manifestations of systemic sclerosis), 14.05E (Repeated manifestations of polymyositis or dermatomyositis), 14.06B (Repeated manifestations of undifferentiated or mixed connective tissue disease), 14.07C (Repeated manifestations of an immune deficiency disorder),	Farraye, F. A., Melmed, G. Y., Lichtenstein, G. R., & Kane, S. V. (2017). ACG clinical guidelines: Preventative care in inflammatory bowel disease. American Journal of Gastroenterology, 112(2), 241-258. Gajendran, M., Loganathan, P., Catinella, A. P., & Hashash, J. G. (2018).

		14.09D (Repeated manifestations of inflammatory arthritis), 14.10B (Sjögren's syndrome), and 14.11I (Repeated manifestations of HIV infection).	A comprehensive review and update on Crohn's disease. Disease-a-Month, 64, 20-57. Rubin, D. T., Ananthakrishnan, A. N., Siegel, C. A., Sauer, B. G., & Long, M. D. (2019). ACG clinical guidelines: Ulcerative colitis in adults. American Journal of Gastroenterology, 114(3), 384-413. Yarur, A. J., Strobel, S. G., Deshpande, A. R., & Abreu, M. T. (2011). Predictors of aggressive inflammatory bowel disease. Gastroenterology & Hepatology

			, 7(10), 652-659.
Listing 5.07/105.07 Intestinal failure			
5.07/105.07 Short bowel syndrome (SBS), due to surgical resection of more than one-half of the small intestine, with dependence on daily parenteral nutrition via a central venous catheter (see 5.00F).	5.07/105.07 Intestinal failure (see 5.00E) due to short bowel syndrome, chronic motility disorders, or extensive small bowel mucosal disease, resulting in dependence on daily parenteral nutrition via a central venous catheter for at least 12 months.	The revised listing more broadly addresses intestinal failure with need for parenteral nutrition and covers a greater range of chronic dysmotility or absent motility disorders. We adopted a public comment requesting this change to account for individuals who have intestinal conditions that may exist without the surgery requirement of short bowel syndrome (the current listing).	Public comment: https://www.regulations.gov/comment/SSA-2017-0042-0015 Thompson JS, Rochling FA, Weseman RA, Mercer DF. Current management of short bowel syndrome. *Curr Probl Surg* 49:52-115, 2012. https://doi.org/10.1067/j.cpsurg.2011.10.002 Pironi, L., Arends, J., Baxter, J., Bozzetti, F., Peláez, R. B., Cuerda, C., Forbes, A., Gabe, S., Gillanders, L., Holst, M., Jeppesen, P. B., Joly, F., Kelly, D., Klek, S., Irtun, Ø., Olde Damink, S. W.,

			Panisic, M., Rasmussen, H. H., Staun, M., Szczepanek, K., … Acute Intestinal Failure Special Interest Groups of ESPEN (2015). ESPEN endorsed recommendations. Definition and classification of intestinal failure in adults. *Clinical nutrition (Edinburgh, Scotland)*, *34*(2), 171–180. https://doi.org/10.1016/j.clnu.2014.08.017 Pironi, L., Arends, J., Bozzetti, F., Cuerda, C., Gillanders, L., Jeppesen, P. B., Joly, F., Kelly, D., Lal, S., Staun, M., Szczepanek, K., Van Gossum, A., Wanten, G., Schneider,

			S. M., & Home Artificial Nutrition & Chronic Intestinal Failure Special Interest Group of ESPEN (2016). ESPEN guidelines on chronic intestinal failure in adults. *Clinical nutrition (Edinburgh, Scotland)*, *35*(2), 247–307. https://doi.org/10.1016/j.clnu.2016.01.020 Deutsch, L., Cloutier, A., & Lal, S. (2020). Advances in chronic intestinal failure management and therapies. *Current opinion in gastroenterology*, *36*(3), 223–229. https://doi.org/10.1097/MOG.0000000000000631 Pierret, A., Wilkinson, J. T., Zilbauer,

			M., & Mann, J. P. (2019). Clinical outcomes in pediatric intestinal failure: a meta-analysis and meta-regression. *The American journal of clinical nutrition*, *1 10*(2), 430–436. https://doi.org/10.1093/ajcn/nqz110
Listing 105.10 Need for supplemental daily enteral feeding via a gastrostomy, duodenostomy, or jejunostomy			
105.10 Need for supplemental daily enteral feeding via a gastrostomy due to any cause, for children who have not attained age 3; thereafter, evaluate the residual impairment(s) (see 105.00H).	105.10 Need for supplemental daily enteral feeding via a gastrostomy, duodenostomy, or jejunostomy (see 105.00H) due to any cause, for children who have not attained age 3; after that, evaluate the residual impairment(s).	The revised listing expands the alternative method of supplemental daily enteral nutrition to meet the listing to include duodenostomy and jejunostomy. We added these two additional methods of tube feeding after we received public comment requesting that we expand tube feedings to those beyond gastric which are often required in patients with digestive disorders.	Public comment: https://www.regulations.gov/comment/SSA-2017-0042-0008

SKIN DISORDERS

The following table summarizes the current and revised sections of the adult skin disorders introductory text and listings.

Sections of the Adult Introductory Text and Listings for Skin Disorders Prior to the Effective Date of this Final Rule	**Revised Sections of the Adult Introductory Text and Listings for Skin Disorders**
Introductory Text, 8.00	

A. What skin disorders do we evaluate with these listings?	A. Which skin disorders do we evaluate under these listings?
B. What documentation do we need?	[8.00C]
[8.00C]	B. What are our definitions for the following terms used in this body system?
C. How do we assess the severity of your skin disorder(s)?	[8.00D]
[8.00B]	C. What evidence do we need to evaluate your skin disorder?
D. How do we assess impairments that may affect the skin and other body systems?	[8.00H]
[8.00C]	D. How do we evaluate the severity of skin disorders?
E. How do we evaluate genetic photosensitivity disorders?	E. How do we evaluate genetic photosensitivity disorders under 8.07?
F. How do we evaluate burns?	F. How do we evaluate burns under 8.08?
G. How do we determine if your skin disorder(s) will continue at a disabling level of severity in order to meet the duration requirement?	[8.00D]
[8.00C]	G. How do we evaluate chronic conditions of the skin or mucous membranes under 8.09?
H. How do we assess your skin disorder(s) if your impairment does not meet the requirements of one of these listings?	[8.00I]
[8.00D]	H. How do we evaluate disorders in other body systems that affect the skin?
[8.00H]	I. How do we evaluate skin disorders that do not meet one of these listings?
Listings	
8.01 Category of Impairments, Skin Disorders	8.01 Category of Impairments, Skin Disorders
8.02 Ichthyosis	8.02 [Reserved] [Now evaluated in 8.09]
8.03 Bullous disease	8.03 [Reserved] [Now evaluated in 8.09]
8.04 Chronic infections of the skin or mucous membranes	8.04 [Reserved] [Now evaluated in 8.09]
8.05 Dermatitis	8.05 [Reserved] [Now evaluated in 8.09]
8.06 Hidradenitis suppurativa	8.06 [Reserved] [Now evaluated in 8.09]
8.07 Genetic photosensitivity disorders	8.07 Genetic photosensitivity disorders
8.08 Burns	8.08 Burns
[8.02-8.06]	8.09 Chronic conditions of the skin or mucous membranes

The following table summarizes the current and revised sections of the childhood skin disorders introductory text and listings.

Sections of the Childhood Introductory Text and Listings for Skin Disorders Prior to the Effective Date of this Final Rule	Revised Sections of the Childhood Introductory Text and Listings for Skin Disorders
Introductory Text, 108.00	
A. What skin disorders do we evaluate with these listings?	A. Which skin disorders do we evaluate under these listings?
B. What documentation do we need?	[108.00C]
[108.00C]	B. What are our definitions for the following terms used in this body system?
C. How do we assess the severity of your skin disorder(s)?	[108.00D]
[108.00B]	C. What evidence do we need to evaluate your skin disorder?
D. How do we assess impairments that may affect the skin and other body systems?	[108.00H]
[108.00C]	D. How do we evaluate the severity of skin disorders?
E. How do we evaluate genetic photosensitivity disorders?	E. How do we evaluate genetic photosensitivity disorders under 108.07?
F. How do we evaluate burns?	F. How do we evaluate burns under 108.08?
G. How do we determine if your skin disorder(s) will continue at a disabling level of severity in order to meet the duration requirement?	[108.00D]
[108.00C]	G. How do we evaluate chronic conditions of the skin or mucous membranes under 108.09?
H. How do we assess your skin disorder(s) if your impairment does not meet the requirements of one of these listings?	[108.00I]
[108.00D]	H. How do we evaluate disorders in other body systems that affect the skin?
[108.00H]	I. How do we evaluate skin disorders that do not meet one of these listings?
Listings	
108.01 Category of Impairments, Skin Disorders	108.01 Category of Impairments, Skin Disorders
108.02 Ichthyosis	108.02 [Reserved] [Now evaluated in 108.09]
108.03 Bullous disease	108.03 [Reserved] [Now evaluated in 108.09]
108.04 Chronic infections of the skin or mucous membranes	108.04 [Reserved] [Now evaluated in 108.09]
108.05 Dermatitis	108.05 [Reserved] [Now evaluated in 108.09]

108.06 Hidradenitis suppurativa	108.06 [Reserved] [Now evaluated in 108.09]
108.07 Genetic photosensitivity disorders	108.07 Genetic photosensitivity disorders
108.08 Burns	108.08 Burns
[108.02-108.06]	108.09 Chronic conditions of the skin or mucous membranes

The following table shows our changes to the adult and childhood skin disorders listings criteria that involve changes to healthcare utilization and condition/episode requirements, the rationale for each change, and supporting resources.

Adult and Childhood Skin Disorders Listings Criteria– Changes in Healthcare Utilization and Condition/Episode Requirements			
Introductory Text or Listing Criteria Prior to the Effective Date of this Final Rule	Revised Introductory Text or Listing Criteria	Rationale	Resources
Introductory Text – 8.00/108.00			
No current introductory text	8.00D5/108.00D5 c. Treatment with PUVA (psoralen and ultraviolet A (UVA) light) or biologics. If you receive additional treatment with PUVA or biologics to treat your skin disorder(s), we will defer adjudication of your claim for 6 months from the start of treatment with PUVA or biologics to evaluate the effectiveness of these treatments unless we can make a fully favorable determination or decision on another	The revised introductory text about deferment for PUVA treatment is supported by medical research. PUVA treatment involves exposure to UVA light after taking biologic medication called psoralen that increases the skin's sensitivity to ultraviolent light. PUVA is generally used under medical supervision when other conservative treatments for skin disorders have proven to be ineffective. We defer adjudication for 6 months from the start of treatment to assess the effectiveness of PUVA treatment on the skin condition.	Farahnik, B., Nakamura, M., Singh, R. K., Abrouk, M., Zhu, T. H., Lee, K. M., … Liao, W. (2016). The patient's guide to psoriasis treatment. Part 2: PUVA phototherapy. Dermatology and Therapy, 6(3), 315-324. https://doi.org/10.1007/s13555-016-0130-9

	basis.		Ong, S., & Venning, V. (2014). PUVA treatment information for patients. Retrieved from Oxford University Hospital NHS website: https://www.ouh.nhs.uk/patient-guide/leaflets/files/120719puva.pdf Shenoi, S. D., & Prabhu, S. (2014). Photochemotherapy (PUVA) in psoriasis and vitiligo. Indian Journal of Dermatology, Venereology and Leprology, 80(6), 497-504. https://doi.org/10.4103/0378-6323.144143
8.07/108.07 Genetic photosensitivity disorders			
8.07/108.07 Genetic photosensitivity disorders, established as described in 8.00E and 108.00E.	8.07/108.07 Genetic photosensitivity disorders, established as described in 8.00E	The requirement that the claimant's skin disorder results in significant functional limitations lasting a minimum of 12 months	44 FR 18170, 18187 (1979), 45 FR 55566,

B. Other genetic photosensitivity disorders, with: 1. Extensive skin lesions that have lasted or can be expected to last for a continuous period of at least 12 months, OR 2. Inability to function outside of a highly protective environment for a continuous period of at least 12 months (see 8.00E2 and 108.00E2).	and 108.00E. The requirements of this listing are met if either paragraph A or paragraph B is satisfied. B. Other genetic photosensitivity disorders (see 8.00E2 and 108.00E2) with either 1 or 2: 2. Chronic skin lesions (see 8.00B2 and 108.00B2) or contractures (see 8.00B3 and 108.00B3) causing chronic pain or other physical limitation(s) that result in impairment-related functional limitations (see 8.00D2 and 108.00D2), as evidenced by: a. Inability to use both upper extremities to the extent that neither can be used to independently initiate, sustain, and complete work-related activities (or age-appropriate activities in childhood claims) involving fine and gross movements (see 8.00B5 and 108.00B5) due to	dates back to 1979.[10] The language in the revised listing reflects a continuation of this requirement, stating that we must have medically documented evidence of physical limitation(s) of functioning related to the claimant's skin disorder, and that the decrease in physical function resulting from the claimant's skin disorder must have lasted, or can be expected to last, for a continuous period of at least 12 months. The revised functional criteria focus on the person's ability to use their upper and lower extremities to perform work-related activities or engage in age-appropriate activities in childhood claims. These revisions reflect our continued focus on the functional limitations that skin disorders may cause and reflect a level of functional limitation similar to the criteria in our current rules. We clarify our policy by providing precise functional criteria rather than examples as in the current skin disorders listings to ensure that adjudicators do not overlook the functional criteria and that we evaluate functional limitations caused by a person's skin impairment in a consistent manner across cases. Additionally, the revised requirement that the claimant have significant limitations in the use of	55607 (1980), and 50 FR 50068, 50098 (1985). Falder, S., Browne, A., Edgar, D., Staples, E., Fong, J., Rea, S., & Wood, F. (2009). Core outcomes for adult burn survivors: A clinical overview. Burns, 35(5), 618-641. https://doi.org/10.1016/j.burns.2008.09.002; Haslik, W., Kamolz, L., Manna, F., Hladik, M., Rath, T., & Frey, M. (2010). Management of full-thickness skin defects in the hand and wrist region: First long-term experiences with the dermal matrix

[10] The introductory text to our 1979 final rule stated that the claimant's skin lesions "must be shown to have persisted for a sufficient period of time despite therapy for a reasonable presumption to be made that severe impairment will last for a continuous period of at least 12 months." 44 FR at 18787.

	chronic skin lesions (see 8.00B2 and 108.00B2) or contractures (see 8.00B3 and 108.00B3); or b. Inability to use one upper extremity to independently initiate, sustain, and complete work-related activities (or age-appropriate activities in childhood claims) involving fine and gross movements (see 8.00B5 and 108.00B5) due to chronic skin lesions (see 8.00B2 and 108.00B2) or contractures (see 8.00B3 and 108.00B3), and a documented medical need (see 8.00B4 and 108.00B4) for an assistive device (see 8.00B1 and 108.00B1) that requires the use of the other upper extremity; or c. Inability to stand up from a seated position and maintain an upright position to the extent needed to independently initiate, sustain, and complete work-related activities (or age-appropriate activities in childhood claims) due to chronic skin lesions (see 8.00B2 and 108.00B2) or contractures (see	two extremities is consistent with the level of functional limitations set forth in other listing criteria, such as in our neurological disorders listings (11.00/111.00), which require "disorganization of motor function" in two extremities.	Matriderm®. Journal of Plastic, Reconstructive & Aesthetic Surgery, 63(2), 360-364. https://doi.org/10.1016/j.bjps.2008.09.026; Wasiak, J., Lee, S., Paul, E., Mahar, P., Pfitzer, B., Spinks, A., . . . Gabbe, B. (2014). Predictors of health status and health-related quality of life 12 months after severe burn. Burns, 40(4), 568-574; 81 FR 43048 (2016)

	8.00B3 and 108.00B3) affecting at least two extremities (including when limitations are due to involvement of the perineum or the inguinal region); or d. Inability to maintain an upright position while standing or walking to the extent needed to independently initiate, sustain, and complete work-related activities (or age-appropriate activities in childhood claims), due to chronic skin lesions (see 8.00B2 and 108.00B2) or contractures (see 8.00B3 and 108.00B3) affecting both lower extremities (including when the limitations are due to involvement of the perineum or the inguinal region).		
Listing 8.08/108.08 Burns			
8.08/108.08 Burns, with extensive skin lesions that have lasted or can be expected to last for a continuous period of at least 12 months (see 8.00F and 108.00F).	8.08/108.08 Burns (see 8.00F and 108.00F). Burns that do not require continuing surgical management (see 8.00B6 and 108.00B6), or that have been documented by an acceptable medical source to have reached maximum therapeutic	The requirement that the claimant's skin disorder results in significant functional limitations lasting a minimum of 12 months dates back to 1979.[11] The language in the revised listing reflects a continuation of this requirement, stating that we must have medically documented evidence of physical limitation(s) of functioning related to the	44 FR 18170, 18187 (1979), 45 FR 55566, 55607 (1980), and 50 FR 50068, 50098 (1985).

[11] Id.

	benefit and therefore are no longer receiving surgical management, resulting in chronic skin lesions (see 8.00B2 and 108.00B2) or contractures (see 8.00B3 and 108.00B3) causing chronic pain or other physical limitation(s) that result in impairment-related functional limitations (see 8.00D2 and 108.00D2), as evidenced by: The functional criteria set forth above in listings 8.07B2a through d and 108.07B2a through d.	claimant's skin disorder, and that the decrease in physical function resulting from the claimant's skin disorder must have lasted, or can be expected to last, for a continuous period of at least 12 months. The revised functional criteria, focus on the person's ability to use their upper and lower extremities to perform work-related activities or engage in age-appropriate activities in childhood claims. These revisions reflect our continued focus on the functional limitations that skin disorders may cause and reflect a level of functional limitation similar to the criteria in our current rules. We clarify our policy by providing precise functional criteria rather than examples as in the current skin disorders listings to ensure that adjudicators do not overlook the functional criteria and that we evaluate functional limitations caused by a person's skin impairment in a consistent manner across cases. Additionally, the revised requirement that the claimant have significant limitations in the use of two extremities is consistent with the level of functional limitations set forth in other listing criteria, such as in our neurological disorders listings (11.00/111.00), which require "disorganization of motor function" in two extremities.	Falder, S., Browne, A., Edgar, D., Staples, E., Fong, J., Rea, S., & Wood, F. (2009). Core outcomes for adult burn survivors: A clinical overview. Burns, 35(5), 618-641. https://doi.org/10.1016/j.burns.2008.09.002; Haslik, W., Kamolz, L., Manna, F., Hladik, M., Rath, T., & Frey, M. (2010). Management of full-thickness skin defects in the hand and wrist region: First long-term experiences with the dermal matrix Matriderm®. Journal of Plastic, Reconstructive & Aesthetic Surgery, 63(2), 360-364. https://doi.org/10.1016/j.bjps.2008.09.026; Wasiak,

			J., Lee, S., Paul, E., Mahar, P., Pfitzer, B., Spinks, A., . . . Gabbe, B. (2014). Predictors of health status and health-related quality of life 12 months after severe burn. Burns, 40(4), 568-574; 81 FR 43048 (2016)
Listing 8.09/108.09 Chronic conditions of the skin or mucous membranes			
No current listing. Note that current listings 8.02/108.02 (Ichthyosis), 8.03/108/03 (Bullous disease), 8.04 (Chronic infections of the skin or mucous membranes), 8.05 (Dermatitis), and 8.06 (Hidradenitis suppurativa) all require extensive skin lesions that persist for at least 3 months despite continued treatment as prescribed. Under the revised skin disorders listings, all of these skin conditions will be	8.09/108.09 Chronic conditions of the skin or mucous membranes (see 8.00G and 108.00G) resulting in: A. Chronic skin lesions (see 8.00B2 and 108.00B2) or contractures (see 8.00B3 and 108.00B3) causing chronic pain or other physical limitation(s) that persist despite adherence to prescribed medical treatment for 3 months	We consolidated the current listings into one listing for adjudicative ease and to more efficiently capture adults and children with chronic skin conditions of listing-level severity. The requirement that the claimant's skin disorder results in significant functional limitations lasting a minimum of 12 months dates back to 1979.[12] The language in the revised listing reflects a continuation of this requirement, stating that we must have medically documented evidence of physical limitation(s) of	20 CFR 404.1509 and 416.909 44 FR 18170, 18187 (1979), 45 FR 55566, 55607 (1980), and 50 FR 50068, 50098 (1985). Falder, S., Browne, A.,

[12] Id.

evaluated under listing 8.09/108.09.	(see 8.00D5b and 108.00D5b. AND Impairment-related functional limitations demonstrated by the functional criteria set forth above in listings 8.07B2a through d and 108.07B2a through d.	functioning related to the claimant's skin disorder, and that the decrease in physical function resulting from the claimant's skin disorder must have lasted, or can be expected to last, for a continuous period of at least 12 months. The revised functional criteria focus on the person's ability to use their upper and lower extremities to perform work-related activities or engage in age-appropriate activities in childhood claims. These revisions reflect our continued focus on the functional limitations that skin disorders may cause and reflect a level of functional limitation similar to the criteria in our current rules. We clarify our policy by providing precise functional criteria rather than examples as in the current skin disorders listings to ensure that adjudicators do not overlook the functional criteria and that we evaluate functional limitations caused by a person's skin impairment in a consistent manner across cases. Additionally, the revised requirement that the claimant have significant limitations in the use of two extremities is consistent with the level of functional limitations set forth in other listing criteria, such as in our neurological disorders listings (11.00/111.00), which require "disorganization of motor function" in two extremities.	Edgar, D., Staples, E., Fong, J., Rea, S., & Wood, F. (2009). Core outcomes for adult burn survivors: A clinical overview. Burns, 35(5), 618-641. https://doi.org/10.1016/j.burns.2008.09.002; Haslik, W., Kamolz, L., Manna, F., Hladik, M., Rath, T., & Frey, M. (2010). Management of full-thickness skin defects in the hand and wrist region: First long-term experiences with the dermal matrix Matriderm®. Journal of Plastic, Reconstructive & Aesthetic Surgery, 63(2), 360-364. https://doi.org/10.1016/j.bjps.2008.09.026; Wasiak, J., Lee, S., Paul, E.,

			Mahar, P., Pfitzer, B., Spinks, A., . . . Gabbe, B. (2014). Predictors of health status and health-related quality of life 12 months after severe burn. Burns, 40(4), 568-574; 81 FR 43048 (2016)

The following table shows our changes to references to BMI in other body systems. Prior to the effective date of this final rule, the formulas for calculating BMI are referenced as appearing in 5.00G and 105.00G2c in various listings, and we are correcting these references to reflect the revised digestive disorders listings.

Listing paragraph	**Introductory Text Prior to the Effective Date of this Final Rule**	**Revised Introductory Text with Updated Cross-References**
6.00C7	*Anorexia (diminished appetite) with weight loss.* Anorexia is a frequent sign of CKD and can result in weight loss. We will use body mass index (BMI) to determine the severity of your weight loss under 6.05B4. (BMI is the ratio of your measured weight to the square of your measured height.) The formula for calculating BMI is in section 5.00G.	*Anorexia (diminished appetite) with weight loss*. Anorexia is a frequent sign of CKD and can result in weight loss. We will use body mass index (BMI) to determine the severity of your weight loss under 6.05B4. (BMI is the ratio of your measured weight to the square of your measured height.) We calculate your BMI using the formulas in the digestive disorders body system (5.00).
14.00F5	*Measurement of CD4 and either body mass index or hemoglobin (14.11G).* To evaluate your HIV	*Measurement of CD4 and either body mass index or hemoglobin (14.11G).* To evaluate your HIV infection

	infection under 14.11G, we require one measurement of your absolute CD4 count or your CD4 percentage, *and* either a measurement of your body mass index (BMI) or your hemoglobin. These measurements must occur within the period we are considering in connection with your application or continuing disability review. If you have more than one measurement of your CD4 (absolute count or percentage), BMI, or hemoglobin within this period, we will use the lowest of your CD4 (absolute count or percentage), BMI, or hemoglobin. The date of your lowest CD4 (absolute count or percentage) measurement may be different from the date of your lowest BMI or hemoglobin measurement. We calculate your BMI using the formulas in 5.00G2.	under 14.11G, we require one measurement of your absolute CD4 count or your CD4 percentage, and either a measurement of your body mass index (BMI) or your hemoglobin. These measurements must occur within the period we are considering in connection with your application or continuing disability review. If you have more than one measurement of your CD4 (absolute count or percentage), BMI, or hemoglobin within this period, we will use the lowest of your CD4 (absolute count or percentage), BMI, or hemoglobin. The date of your lowest CD4 (absolute count or percentage) measurement may be different from the date of your lowest BMI or hemoglobin measurement. We calculate your BMI using the formulas in the digestive disorders body system (5.00).
100.00C2c	BMI is the ratio of a child's weight to the square of his or her height. We calculate BMI using the formulas in 105.00G2c.	BMI is the ratio of a child’s weight to the square of his or her height. We calculate BMI using the formulas in the digestive disorders body system (105.00).
103.00K2c	BMI is the ratio of a child's weight to the square of his or her height. We calculate BMI using the formulas in 105.00G2c.	BMI is the ratio of a child’s weight to the square of his or her height. We calculate BMI using the formulas in the digestive disorders body system (105.00).
104.00C3b(iii)	BMI is the ratio of a child's weight to the square of his or her height. We calculate BMI using the formulas in 105.00G2c.	BMI is the ratio of a child’s weight to the square of his or her height. We calculate BMI using the formulas in the digestive disorders body system (105.00).
106.00C5b(iii)	BMI is the ratio of a child's weight to the square of his or her height. We calculate BMI using the formulas in 105.00G2c.	BMI is the ratio of a child’s weight to the square of his or her height. We calculate BMI using the formulas in the digestive disorders body system (105.00).
114.00F7b(iii)	BMI is the ratio of a child's weight to the square of his or her height.	BMI is the ratio of a child’s weight to the square of his or her height. We

	We calculate BMI using the formulas in 105.00G2c.	calculate BMI using the formulas in the digestive disorders body system (105.00).

We are making several changes from the NPRM to this final rule for digestive disorders and skin disorders:

- The following is a high-level summary of the major changes from the NPRM to this final rule. Below, in the section titled *Public Comments on the NPRM*, we describe in greater detail our response to questions and public comments, as well as changes from the NPRM to this final rule. Further, these responses provide additional details about our rule changes from our current rules, through the NPRM, and to our final rule for digestive disorders and skin disorders.
- We also made minor, editorial changes from the NPRM for clarity and readability throughout both digestive disorders and skin disorders.

DIGESTIVE DISORDERS

- **Hepatopulmonary syndrome**: We revised the regulatory text for hepatopulmonary syndrome to describe relevant clinical findings associated with this complication of chronic liver disease (CLD) (5.00C2 and 105.00C2 (*Manifestations of CLD*)).
- **SSA Chronic Liver Disease (SSA CLD) and SSA Chronic Liver Disease-Pediatric (SSA CLD-P) scores**: In the introductory text to the listing, we modified the SSA CLD calculation. We added a sentence to clarify that if you have the two SSA CLD scores required by 5.05G ("Two SSA CLD scores") and 105.05G1 ("For children age 12 and older"), we will find that your impairment meets the criteria of the listing from at least the date of the first SSA CLD score

(5.00C3 (*SSA Chronic Liver Disease (SSA CLD) score*) and 105.00C3 (*SSA Chronic Liver Disease (SSA CLD) and SSA Chronic Liver Disease-Pediatric (SSA CLD-P) scores*); 5.05G ("Two SSA CLD scores") and 105.05G1 ("For children age 12 or older"). We also removed the reference to SSA CLD-P scores in 105.05G1 ("For children age 12 or older").

- **Inflammatory bowel disease (IBD)**: In the listing introductory text, we added perianal disease and extraintestinal manifestations with examples for each. We also clarified the consideration of surgical diversion of the intestinal tract (5.00D and 105.00D (*What is inflammatory bowel disease (IBD), and how do we evaluate it under 5.06/105.06*)). We retained the consideration of anemia and serum albumin from the current criteria in revised listings 5.06B1, 5.06B2, 105.06B1 and 105.06B2.
- **Supplemental nutrition**: We expanded the listing introductory text and criteria for the alternative method of supplemental daily enteral nutrition to meet the listing to include duodenostomy or jejunostomy (5.06B and 105.06B ("Two of the following occurring within a consecutive 12-month period") and 105.10 (*Need for supplemental daily enteral feeding via a gastrostomy, duodenostomy, or jejunostomy*)).
- **Intestinal failure**: We expanded the listing introductory text and criteria for short bowel syndrome (SBS) to include intestinal failure and added descriptions of different types of intestinal failure (5.00E and 105.00E (*What is intestinal failure, and how do we evaluate it under 5.07/105.07?*); 5.07 and 105.07 (*Intestinal failure*)).
- **Weight loss due to any digestive disorder**: We retained the current criteria, for weight loss due to any digestive disorder, rather than finalizing the proposed criteria for malnutrition due to any digestive disorder (5.00F (*How do we evaluate*

weight loss due to any digestive disorder under 5.08?) and 5.08 (*Weight loss due to any digestive disorder*)). Although it is not a policy change, in this final rule, we also updated the language in the listing text to refer to "adherence to prescribed medical treatment" instead of "continuing treatment as prescribed," for consistency with medical terminology and the changes we made to the skin disorders listings. Additionally, we added language to the introductory text in 5.00F (*How do we evaluate weight loss due to any digestive disorder under 5.08?*) and 105.00F (*How do we evaluate growth failure due to any digestive disorder under 105.08?*) to explain how we consider weight loss or growth failure due to impairments other than digestive disorders.

- **Chronic liver disease**: We reorganized the criteria in 5.05A and 105.05A ("Hemorrhaging from esophageal, gastric, or ectopic varices") to use an outline format rather than text paragraphs. We did this to improve clarity and readability, but there were no substantive changes to the criteria.
- **References to BMI in other body systems**: As we finalize revisions to the digestive disorders listings, we are revising cross references in other body systems to correct citations to the BMI formula because they will be outdated once this rule is effective. Specifically, we made these revisions to 6.00C7, 14.00F5, 100.00C2c, 103.00K2c, 104.00C3b(iii), 106.00C5b(iii), and 114.00F7b(iii).

SKIN DISORDERS

- **Definitions**: We added assistive devices used in a seated position to the list of examples of assistive devices. We also added a definition for exacerbation (8.00B and 108.00B (*What are our definitions for the following terms used in this body system?*)).

- **Evidence**: We clarified that we consider any available history of familial incidence (8.00C and 108.00C (*What evidence do we need to evaluate your skin disorder?*)).
- **Functional criteria**: We clarified that the inability to perform fine and gross movements is due to chronic skin lesions or contractures, consistent with the other two functional criteria (8.00D2 and 108.00D2 (*Limitation(s) of physical functioning due to skin disorders*)).
- **Adherence to prescribed treatment**: We changed the term "physician" to "medical source" in 8.00D5b and 108.00D5b (*Despite adherence to prescribed medical treatment for 3 months*) to include treatment prescribed by any medical source.[13]
- **Burns**: We removed the "third-degree" qualifier in front of burns (8.00F and 108.00F (*How do we evaluate burns under 8.08/108.08*); 8.08 and 108.08 (*Burns*)).
- **Improving Clarity and Readability**: We revised the language in 8.07B2 and 108.07B2 ("Chronic skin lesions or contractures"), 8.08 and 108.08 (*Burns*), and 8.09 and 108.09 (*Chronic conditions of the skin or mucous membranes*) to remove repetitive language and make the criteria easier to understand and apply.

Public Comments on the NPRM

In the NPRM, we provided the public with a 60-day comment period, which ended on September 23, 2019. We received 14 comments. The comments came from advocacy groups, legal services organizations, a State agency that makes disability determinations for us, medical organizations, and individual commenters. Multiple

[13] 20 CFR 404.1502(d) and 416.902(i).

commenters provided identical (or very similar) comments and recommendations.

We carefully considered all of the comments related to this rulemaking. We have tried to summarize the commenters' views accurately and have responded to all of the significant issues raised by the commenters that were within the scope of this rule. We have not summarized or responded to comments that were outside the scope of the proposed rule. Some commenters noted provisions with which they agreed but did not make suggestions for changes in those provisions. We did not summarize or respond to those comments.

Digestive Disorders

Chronic Liver Disease (CLD)

Comment: Two commenters suggested that we use the Model for End-Stage Liver Disease (MELD) formula rather than the SSA CLD formula. One commenter suggested we use the MELD formula so we could keep pace with changes in the treatment of digestive disorders without having to update our regulations. Another commenter noted that even when SSA CLD scores are available in the medical record, they are not used by SSA adjudicators, and requested that we use the SSA CLD scores when available. The commenter suggested that if the SSA CLD is unavailable, we use the MELD scores when available in the medical record.

Response: We partially adopted this comment. In the 2007 *Revised Medical Criteria for Evaluating Digestive Disorders* final rule, we explained that the MELD is a numerical scale developed for the United Network for Organ Sharing (UNOS) that is used to determine a person's placement on the liver transplant list within the Organ Procurement and Transplant Network (OPTN).[14] The MELD score is based on objective and verifiable medical data and estimates a person's risk of dying while waiting for a

[14] 72 FR 59398 (2007).

liver transplant. In 2016, the MELD formula was modified to take serum sodium levels into account under certain situations.[15,16]

The SSA CLD calculation under the current rules was the mathematical equivalent to the MELD formula used in 2007, and we initially proposed no changes to this calculation in the NPRM.[17,18] However, in response to comments that we adopt the MELD formula, we reviewed the updated 2016 MELD formula and assessed its use in our disability program. We learned that for people with certain chronic liver diseases, formulas utilizing serum sodium levels predict negative outcomes more accurately than formulas that do not consider serum sodium levels.[19,20] As a result, we modified the SSA CLD calculation to also account for serum sodium levels under certain situations, so it remains mathematically equivalent to the new MELD calculation. However, we did not directly adopt the commenters' suggestion that we reference the MELD score in our listing criteria, for reasons explained below.

As demonstrated in the table below, the SSA CLD and the MELD are nearly identical, aside from the placement of a multiplier. Despite this difference, the two formulas yield identical results.

MELD	SSA CLD

[15] Organ Procurement and Transplantation Network & United Network for Organ Sharing. (2015). Changes to OPTN bylaws and policies from actions at OPTN/UNOS Executive Committee meetings July 2015-November 2015 [PDF]. https://optn.transplant.hrsa.gov/media/1575/policynotice_20151101.pdf

[16] United Network for Organ Sharing. (2016). Policy and system changes effective January 11, 2016, adding serum sodium to MELD calculation. https://unos.org/news/policy-and-system-changes-effective-january-11-2016-adding-serum-sodium-to-meld-calculation/

[17] 72 FR 59398 (2007).

[18] 84 FR 35936 (2019).

[19] Vaa, B. E., Asrani, S. K., Dunn, W., Kamath, P. S., & Shah, V. H. (2011). Influence of serum sodium on MELD-based survival prediction in alcoholic hepatitis. *Mayo Clinic Proceedings, 86*(1), 37-42. https://doi.org/10.4065/mcp.2010.0281

[20] Londoño, M.-C., Cárdenas, A., Guevara, M., Quintó, L., de las Heras, D., Navasa, M., Rimola, A., Garcia-Valdecasas, J.-C., Arroya, V., & Ginès, P. (2007). MELD score and serum sodium in the prediction of survival of patients with cirrhosis awaiting liver transplantation. *Gut, 56*(9), 1283-1290. https://doi.org/10.1136/gut.2006.102764

[0.378 * $\log_e$(bilirubin)) + (1.120 * $\log_e$(INR[21])) + (0.957 * $\log_e$(creatinine)) + 0.643] * 10	(3.78 * $\log_e$(bilirubin)) + (11.20 * $\log_e$(INR)) + (9.57 * $\log_e$(creatinine)) + 6.43
If resulting value (MELD(i)) or SSA CLD(i)) is 12 or greater, the serum sodium value is considered in the following way:	
MELD(i) + 1.32 * (137-Na) - [0.033*MELD(i) * (137-Na)]	SSA CLD(i) + 1.32 * (137-Na) - [0.033*SSA CLD(i) * (137-Na)].

We modified the SSA CLD formula rather than directly adopting the MELD formula for multiple reasons. First, we use the SSA CLD score for different purposes than the medical community uses the MELD score. Specifically, MELD scores are used to determine a person's placement on the liver transplant list, while SSA CLD scores are used to determine whether a person's chronic liver disease is severe enough to preclude the performance of any gainful activity. While our analysis shows that the new SSA CLD calculation, which is mathematically equivalent to the current MELD calculation, is appropriate for our programmatic use, going forward, our analysis and research may determine that a SSA CLD calculation which differs from the MELD calculation is more appropriate for a determination of listing-level chronic liver disease. Likewise, the MELD calculation may change in a way that precludes us from using it to determine listing-level chronic liver disease. Because the MELD is maintained by an independent entity, we may not know of the change until it is in effect, and therefore would be tied to using an inappropriate formula until we were able to publish a regulatory change. In such instances, it is important that we retain flexibility and use our own calculation, rather than adopt the MELD formula, as the commenter suggests.

[21] International Normalized Ratio (INR) is a common laboratory test that measures the amount of time it takes for the blood to clot.

Moreover, the SSA CLD has unique testing standards that are consistent with our programmatic requirements. For instance, for the SSA CLD, we require that all laboratory values be obtained within a continuous 30-day period, and we do not use any INR values derived from testing done while the claimant is on anticoagulant treatment. These requirements are not in place for the MELD calculation (see 5.00C3 (*SSA Chronic Liver Disease (SSA CLD) score*) and 105.00C3a (*SSA CLD score*)). Finally, the SSA CLD score is familiar to our adjudicators because we began using it in 2007.

The commenter also misunderstands our use of SSA CLD scores. Because SSA CLD scores result from our regulatory formula, they are generally not available in the medical record, nor do we expect them to be. Instead, adjudicators must calculate the SSA CLD score using a formula that includes up to four laboratory values. The calculation is set forth in our regulations at 5.00C3 (*SSA Chronic Liver Disease (SSA CLD) score*) and 105.00C3a (*SSA CLD score*). Regardless of the formula used, we require the component values be present in the medical evidence of record, and then our adjudicators input those values into a calculator to determine the score based on the regulatory formula.

With regard to our changes to the SSA CLD formula, we describe the modified SSA CLD calculation in the introductory text in this final rule in paragraphs 5.00C3 (*SSA Chronic Liver Disease (SSA CLD) score*) and 105.00C3a (*SSA CLD score*). We reorganized the order of paragraphs 5.00C3b ("For any SSA CLD calculation") and 5.00C3c ("When we indicate '$\log_e$'") and 105.00C3a(ii) ("For any SSA CLD calculation") and 105.00C3a(iii) ("When we indicate '$\log_e$'") for clarity. We updated the instructions for rounding and limits for maximum and minimum values in paragraphs 5.00C3b and 105.00C3a(ii) ("For any SSA CLD calculation") to reflect the addition of serum sodium to the CLD formula. Finally, we updated the CLD calculation examples in

paragraphs 5.00C3c and 105.00C3a(iii) ("When we indicate '$\log_e$'") to reflect the change in the formula.

Comment: One commenter stated that we do not provide evidence that SSA CLD scores greater than or equal to 20 are a measure of the ability or inability to engage in substantial gainful activity (SGA).

Response: We disagree. The rule change reflects medical research showing the increased 3-month mortality risk and overall clinical severity indicated by laboratory values resulting in an SSA CLD score of at least 20.[22,23,24] For instance, individuals with a MELD score ranging from 10-19 have a 3-month mortality rate of 6%, whereas individuals with a MELD score between 20 and 29 have a 3-month mortality rate of 19.6%, which means they are more than three times more likely to die within 3 months if they do not receive a transplant.[25] As explained above, the MELD score is equivalent to the SSA CLD score. This degree of severity is consistent with liver disease that will prevent an adult from engaging in any gainful activity, result in death, or cause marked and severe limitations in children over the age of 12. Clinical practice uses the MELD formula, which we describe above as equivalent to the SSA CLD, to evaluate liver disease for individuals age 12 and older. However, because the formula that our SSA CLD-P score is based on is only used for individuals under age 12, we removed listing criteria considering an SSA CLD-P score of at least 20 from revised listing 105.05G1 ("For children age 12 and older") that was initially included in the NPRM.

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[22] Singal, A. K., & Kamath, P. S. (2012). Model for end-stage liver disease. *Journal of Clinical and Experimental Hepatology, 3*(1), 50-60. https://doi.org/10.1016/j.jceh.2012.11.002

[23] Zhang, E. -L., Zhang, Z. -Y., Wang, S. -P., Xiao, Z. -Y, Gu, J., Xiong, M, Chen, X. -P., & Huang, Z. -Y. (2016). Predicting the severity of liver cirrhosis through clinical parameters. *Journal of Surgical Research, 204*(2), 274-281. https://doi.org/10.1016/j.jss.2016.04.036

[24] Thornton, K. (2021, February 12). Evaluation and Prognosis of Persons with Cirrhosis. *Hepatitis C Online*. https://www.hepatitisc.uw.edu/go/evaluation-staging-monitoring/evaluation-prognosis-cirrhosis/core-concept/all

[25] Id.

The SSA CLD-P is based on the Pediatric Model for End Stage Liver Disease (or the PELD), which was also developed by OPTN, and is used for organ transplant allocation for persons under the age of 12. Unlike the MELD, the PELD has not been changed since prior to the publication of our 2007 revisions to the digestive disorders listings, where we created the SSA CLD-P formula, as an equivalent to the PELD, to evaluate liver disease under listing 105.05G2 ("For children who have not attained age 12").[26] Similar to an SSA CLD score of at least 20, medical research shows an increased 3-month mortality risk and overall clinical severity indicated by laboratory values that result in an SSA CLD-P score of at least 11.[27] This level of severity continues to identify liver disease severe enough to cause marked and severe limitations in children under the age of 12. We therefore did not propose a change to the existing SSA CLD-P formula in the NPRM, nor were there public comments suggesting a revision to our formula based on PELD.

The commenter did not provide any alternatives or suggestions on the revised text. Additionally, the commenter misstates the function of our listings regarding gainful activity by using the phrase "substantial gainful activity." The listings describe impairments that we consider severe enough to prevent an adult from doing any gainful activity.[28] For children, the listings describe impairments we consider severe enough to cause marked and severe functional limitations.[29]

Comment: Several commenters asked us to keep the current listing direction in 5.05G and 105.05G ("End stage liver disease") or replace it with suggested text. The

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[26] 72 FR 59398 (2007).

[27] Chung-Chou, H. C., Bryce, C. L., Shneider, B. L., Yabes, J. G., Ren, Y., Zenarosa, G. L., Tomko, H., Donnell, D. M., Squires, R. H., & Roberts, M. S. (2018). Accuracy of the pediatric end-stage liver disease score in estimating pretransplant mortality among pediatric liver transplant candidates. JAMA Pediatrics, 172(11), 1070-1077. https://doi.org/10.1001/jamapediatrics.2018.2541

[28] 20 CFR 404.1525(a) and 416.925(a).

[29] 20 CFR 416.925(a).

commenters suggested the listing criteria should, "consider [the person] under a disability no later than the date of the first score" for the required two SSA CLD scores.

Response: We agree with the commenters. The current listing language states we "[c]onsider under a disability from at least the date of the first score." While we proposed to remove this direction in the NPRM, we did not intend to change our policy in the current rule that we consider an individual under a disability from at least the date of their first score. At the commenters' request and to avoid confusion on this issue, we are no longer making the change proposed in the NPRM and have retained the current listing direction to "consider under a disability from at least the date of the first score" in listings 5.05G ("Two SSA CLD scores") and 105.05G1 ("For children age 12 or older"). We also included applicable corresponding introductory text in the final rule introductory paragraphs 5.00C3 (*SSA Chronic Liver Disease (SSA CLD) score*) and 105.00C3a (*SSA CLD score*).

Comment: One commenter expressed that our proposed change to listing 5.05G ("Two SSA CLD scores") and 105.05G1 ("For children age 12 or older") constitutes a new requirement for two SSA CLD scores and would make a finding of disability dependent on access to expensive care instead of medical considerations.

Response: We disagree with the characterization that it is a new requirement that two SSA CLD scores are required to make a finding of disability under the listing. Our current rules, at 5.00D11e ("Listing 5.05G requires two SSA CLD scores") and 105.00D11a(v) ("Listing 105.05G requires two SSA CLD scores") state that two SSA CLD scores are required. The language "[c]onsider under a disability from at least the date of the first score" does not mean the second SSA CLD score is optional under 5.05G ("Two SSA CLD scores") or 105.05G1 ("For children age 12 or older").

Comment: One commenter suggested that we clarify the definition of gastrointestinal hemorrhaging, which is necessary to establish listing-level severity. To

that end, the commenter suggested adding information about clinical findings on endoscopy to proposed listing 5.05A ("Hemorrhaging from esophageal, gastric, or ectopic varices").

Response: We did not adopt this comment, because hemodynamic instability findings, and the need for hospitalization for transfusion of at least two units of blood, are the defining characteristics of hemorrhage of listing-level severity under revised listing 5.05A ("Hemorrhaging from esophageal, gastric, or ectopic varices"). Although the underlying hemorrhage documented by imaging is a requirement under revised listing 5.05A ("Hemorrhaging from esophageal, gastric, or ectopic varices"), this imaging alone does not establish listing-level severity. In addition to hemorrhaging from esophageal, gastric, or ectopic varices, or from portal hypertensive gastropathy documented by imaging, listing 5.05A ("Hemorrhaging from esophageal, gastric, or ectopic varices") also requires both the finding of hemodynamic instability and hospitalization for transfusion of at least two units of blood. We consider the suggested endoscopic findings when they are present in the medical evidence.

Comment: Several commenters asked us to allow the use of pulse oximetry results to demonstrate hepatopulmonary syndrome in listings 5.05E and 105.05E ("Hepatopulmonary syndrome"). One commenter expressed concern about the appropriateness of arterial blood gas (ABG) testing (as required under proposed 105.05E1 ("Arterial PaO2 measured by an ABG test")) in young children due to difficulties in administration on young children.

Response: We did not adopt these comments. ABG testing is the widely-accepted standard test for confirmatory diagnosis of hypoxemia in suspected hepatopulmonary syndrome, regardless of the patient's age.[30] Although there can be some difficulties with

[30] Grilo-Bensusan, I., & Pascasio-Acevedo, J. M. (2016). Hepatopulmonary syndrome: What we know and what we would like to know. *World Journal of Gastroenterology, 22*(5), 5728-5741. https://doi.org/10.3748/wjg.v22.i25.5728

administering ABG tests on young children, such as bleeding, risks associated with getting an ABG are relatively minor, and ABG testing remains the most valid indicator of listing-level severity.[31,32,33] Although pulse oximetry is useful to screen a patient for hepatopulmonary syndrome, it is generally not used as a diagnostic test, due to a risk of false positives.[34] The literature cited by the commenters stated that ABG testing would still be required for final determination of hepatopulmonary syndrome severity after any screening with pulse oximetry.[35] Furthermore, pulse oximetry is not as accurate as ABG tests in cases of very low oxygen saturation, and may also be affected by the use of certain cosmetics, skin pigmentation, or poor peripheral circulation.[36]

We consider all evidence in the case record when we evaluate claims for disability benefits, including laboratory test results as a form of objective medical evidence.[37] If an impairment(s) does not satisfy the listing requirement for an ABG measurement, then we will consider whether the impairment(s) medically equals a listing.[38] If an adult's impairment(s) does not meet or medically equal any listing, they can be found disabled at a later step in the sequential evaluation process.[39] If a child's impairment(s) does not meet or medically equal any listing, including because the medical evidence in the record does not contain necessary laboratory test results, we may

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[31] Forde K. A., Fallon M. B., Krowka M. J., Sprys M., Goldberg D. S., Krok K. L., Patel, M., Lin, G., Oh, J. K., Mottram, C. D., Scanlon, P. D., & Kawut S. M. (2019). Pulse oximetry is insensitive for detection of hepatopulmonary syndrome in patients evaluated for liver transplantation. *Hepatology, 69*(1), 270-281. https://doi.org/10.1002/hep.30139

[32] Noli, K., Solomon, M., Golding, F., Charron, M., & Ling, S. C. (2008). Prevalence of hepatopulmonary syndrome in children. *Pediatrics, 121*(3), e522-527. https://doi.org/10.1542/peds.2007-1075

[33] *Arterial Blood Gas (ABG): What It Is, Purpose, Procedure & Levels*. (2022, February 18.). Cleveland Clinic. https://my.clevelandclinic.org/health/diagnostics/22409-arterial-blood-gas-abg

[34] Arguedas, M. R., Singh, H., Faulk, D. K., & Fallon, M. B. (2007). Utility of pulse oximetry screening for hepatopulmonary syndrome. *Clinical Gasteroenterology and Hepatology, 5*(6), 749-754. https://doi.org/10.1016/j.cgh.2006.12.003

[35] Id.

[36] Jubran, A. (2015). Pulse oximetry. *Critical Care, 19*, 272. https://doi.org/10.1186/s13054-015-0984-8

[37] 20 CFR 404.1520, 416.920, and 416.924.

[38] 20 CFR 404.1526 and 416.926.

[39] 20 CFR 404.1520 and 416.920.

find that their impairment(s) functionally equals the listings.[40] It is at this stage that we would use all available medical and non-medical evidence to evaluate whether a child's impairment(s) functionally equals the listings, including pulse oximetry results.

Comment: Several commenters requested that, if we do not permit the use of pulse oximetry results for listings 5.05E and 105.05E ("Hepatopulmonary syndrome"), that we state that we will purchase ABG testing for people with hepatopulmonary syndrome who have pulse oximetry values below 96%.

Response: We did not adopt the comment. We do not require a consultative examination in every case where there is evidence of a pulse oximetry value below 96%. Our regulations governing the purchase of consultative examinations already state that if we cannot obtain the information we need from a claimant's medical sources to make a determination or decision of disability, or when the other available evidence on a claim is insufficient, we may purchase the needed medical examinations or tests, but this is an individualized and fact-specific determination. Therefore, it would be inappropriate, and inconsistent with our regulations, for SSA to purchase ABG testing when there are no inconsistencies in the evidence, or when the evidence in the file is sufficient to make a determination or decision on a claim.[41]

Comment: Commenters requested that we include a statement in listings 5.05E and 105.05E ("Hepatopulmonary syndrome") that hypoxemia due to hepatopulmonary syndrome may also be evaluated under listing 3.02C2 (*Chronic respiratory disorders)* or the childhood respiratory listings. For proposed criterion in listing 5.05E1 ("Arterial P_aO_2 measured by an ABG test"), one commenter asked us to either use both P_aO_2 and P_aCO_2 values, or the highest favorable P_aO_2 for each altitude range, as noted in tables for P_aO_2/P_aCO_2 measurements in the respiratory listing for hypoxemia.

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[40] 20 CFR 416.924.

[41] 20 CFR 404.1519a and 416.919a.

Response: We did not adopt these comments. Hepatopulmonary syndrome is not the same as hypoxemia caused by a chronic respiratory disorder. Hepatopulmonary syndrome is not a respiratory disease. It is a rare complication of liver disease, characterized by arterial deoxygenation due to intrapulmonary vascular dilation and arteriovenous shunting.[42,43] Hypoxemia is defined as a below-normal level of oxygen in the blood, specifically in the arteries.[44] The only effective treatment for hepatopulmonary syndrome is liver transplant. Severity grading of hepatopulmonary syndrome is based on measurements of P_aO_2, not P_aCO_2, and 5.05E1 and 105.05E1 consider altitude when determining whether a claimant's hepatopulmonary syndrome is listing-level severity.[45,46] For these reasons, we are not including a syndrome caused by liver disease in a respiratory listing. However, in the regulatory text of the NPRM and the final rule, we state in paragraphs 5.00J2 and 105.00L2 ("If you have a severe medically determinable impairment(s) that does not meet a listing") that if a person's impairment(s) does not meet the requirements of a listing in any body system, we may find that the impairment(s) is medically equivalent to another listing. An impairment(s) is medically equivalent to a listed impairment if it is at least equal in severity and duration to the criteria of any listed impairment, including those listed in 5.00 and 105.00 (*Digestive Disorders*).[47]

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[42] Taber's Cyclopedic Medical Dictionary – 23rd Ed. (2017).
[43] Gladwin, M. T., & Levine, A. R. (2020, September). *Hepatopulmonary syndrome*. The Merck Manual Professional Version. https://www.merckmanuals.com/professional/pulmonary-disorders/pulmonary-hypertension/hepatopulmonary-syndrome
[44] Taber's Cyclopedic Medical Dictionary – 23rd Ed. (2017).
[45] Rodríguez-Roisin, R., & Krowka, M. J. (1998). Hepatopulmonary syndrome – a liver-induced lung vascular disorder. *The New England Journal of Medicine, 358*, 2378-2387. https://doi.org/10.1056/NEJMra0707185
[46] Grilo-Bensusan, I., & Pascasio-Acevedo, J. M. (2016). Hepatopulmonary syndrome: What we know and what we would like to know. *World Journal of Gastroenterology*, *22*(25), 5728-5741. https://doi.org/10.3748/wjg.v22.i25.5728
[47] 20 CFR 404.1526 and 416.926.

Comment: One commenter suggested we remove proposed criterion 5.05E2 ("Intrapulmonary arteriovenous shunting") as it demonstrates only the presence of hepatopulmonary syndrome and not a level of hypoxemia or severity associated with proposed 5.05E1 ("Arterial PaO2 measured by an ABG test"). The commenter stated that it is not clear that arteriovenous shunting as shown by the contrasted echocardiogram or macroaggregated albumin lung scan required in proposed criterion 5.05E2 ("Intrapulmonary arteriovenous shunting") necessarily equates to the expected severity associated with the required hypoxemia levels in proposed criterion 5.05E1 ("Arterial P_aO_2 measured by an ABG test"). The commenter noted that some of these tests in proposed 5.05E2 ("Intrapulmonary arteriovenous shunting") are not quantitative, and not all of them are specific for intrapulmonary shunting. The commenter asked us to add these tests to the introductory text along with the symptoms of platypnea (shortness of breath relieved when lying down) and orthodeoxia (low arterial blood oxygen in the upright position) that are highly specific for hepatopulmonary syndrome when present alongside chronic liver disease.

Response: We partially adopted the comment. We updated the introductory text at 5.00C2e and 105.00C2e (*Hepatopulmonary syndrome*) to include the clinical findings suggested by the commenter. While we agree with the commenter that the criteria in 5.05E2 and 105.05E2 demonstrate the presence of hepatopulmonary syndrome and not a level of hypoxemia, we kept the criterion because the presence of hepatopulmonary syndrome, as confirmed by these tests, continues to be indicative of listing-level severity. Hepatopulmonary syndrome is a very serious consequence of chronic liver disease, is a

progressive condition, and has a high morbidity and mortality rate associated with it.[48] Currently, the only treatment is a liver transplant.[49]

Inflammatory Bowel Disease

Comment: A number of commenters questioned why "perineal disease" was removed from the list of signs and symptoms of inflammatory bowel disease (IBD) in proposed 5.00D2 ("We evaluate your signs and symptoms of IBD") and urged its inclusion in the final rule.

Response: We adopted this comment. We agree that this is an important complication of IBD; however, the medical community uses the term *perianal* disease to describe the perianal complications that are considered an early sign of IBD.[50] So, we adopted the commenter's suggestion, and changed the terminology to "perianal disease." We added this to the list of signs and symptoms of IBD in the introductory text at 5.00D2 and 105.00D2 ("We evaluate your signs and symptoms of IBD"), and provided examples ("for example, fissure, fistulas, abscesses, and anal canal stenosis") associated with perianal Crohn's disease.

Comment: Commenters recommended that the final version of the listing include the language from current 5.00E3 ("IBD may be associated with significant extraintestinal manifestations in a variety of body systems") about extraintestinal manifestations of IBD.

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[48] SSA has designated hepatopulmonary syndrome as a Compassionate Allowance (CAL) condition. See *Compassionate Allowances website Home Page* (ssa.gov).

[49] Bansal, K., Gore, M., & Mittal, S. (2022). Hepatopulmonary Syndrome. In StatPearls. StatPearls Publishing. https://www.ncbi.nlm.nih.gov/books/NBK562169.

[50] Galandiuk, S., Kimberling, J., Al-Mishlab, T. G., & Stromberg, A. J. (2005). Perianal Crohn disease: Predictors of need for permanent diversion. *Annals of surgery*, *241*(5), 796–802. https://doi.org/10.1097/01.sla.0000161030.25860.c1

Response: We agree with the commenter and added the language from current paragraph 5.00E3 ("IBD may be associated with significant extraintestinal manifestations in a variety of body systems") about extraintestinal manifestations of IBD to paragraph 5.00D4 ("IBD may also be associated with significant extraintestinal manifestations in a variety of body systems"). For consistency between adult and child listings, we also added the corresponding language from current paragraph 105.00E3 ("IBD may be associated with significant extraintestinal manifestations in a variety of body systems") as revised paragraph 105.00D4 ("IBD may be associated with significant extraintestinal manifestations in a variety of body systems"), and renumbered proposed paragraph 105.00D4 as revised paragraph 105.00D5.

Comment: One commenter recommended that the tube feeding description be expanded beyond "gastric" to other types (that is, duodenal or jejunal) that are often required in patients with digestive disorders.

Response: We adopted this comment because the commenter brought a perspective that we had not considered, which was that types of tube feeding which are similar in purpose should be included in the listing, and our research confirmed that supplemental daily enteral nutrition supplied via duodenostomy or jejunostomy is also representative of listing-level severity. [51,52,53] Therefore, we added tube feeding via duodenostomy or jejunostomy to listings 5.06B and 105.06B ("Two of the following occurring within a consecutive 12-month period"), and 105.10 (*Need for supplemental daily enteral feeding via a gastrostomy, duodenostomy, or jejunostomy*). We also

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[51] Pearce, C. B. & Duncan, H. D. (2002). Enteral feeding. Nasogastric, nasojejunal, percutaneous endoscopic gastrostomy, or jejunostomy: its indications and limitations, Postgraduate Medical Journal, 78, 198-204. https://doi.10.1136/pmj.78.918.198

[52] Brett, K. & Argáez, C. (2018). Gastrostomy versus gastrojejunostomy and/or jejunostomy feeding tubes: a review of clinical effectiveness, cost-effectiveness and guidelines. Ottawa (ON): Canadian Agency for Drugs and Technologies in Health.

[53] Clinical Nutrition University. (2021, May 25). Types of Feeding Tubes EXPLAINED. YouTube. https://www.youtube.com/watch?v=4Oam1yUHiO8.

provided guidance about evaluating tube feedings in introductory text sections 5.00D2 and 105.00D2 ("We evaluate your signs and symptoms of IBD") and 105.00H (*How do we evaluate the need for supplemental daily enteral feeding via a gastrostomy, duodenostomy, or jejunostomy?*).

Short Bowel Syndrome and Intestinal Failure

Comment: One commenter agreed with the proposed changes to expand the definition of short bowel syndrome (SBS) to consider "surgical resection of any amount of the small intestine," but suggested we further expand the definition by adding "the continual need for nutritional intervention such as oral rehydration, enteral tube feeding and/or parenteral nutrition is documented."

Response: We did not adopt the comment. The listings describe impairments that we consider severe enough to prevent an adult from doing any gainful activity.[54] The commenter's suggestion includes oral rehydration and enteral tube feeding, which, when associated with SBS or intestinal failure, are not indicative of a condition that is listing-level severity.[55] Since, on their own, these nutritional interventions are not dispositive of a disorder that is severe enough to prevent any gainful activity, we did not expand the definition of SBS as the commenter suggested. However, we do consider evidence of nutritional intervention alongside all other relevant information at later steps in our sequential evaluation process.

Comment: One commenter asked us to expand the criteria for listings 5.07 and 105.07 (*Intestinal failure*) to "support patients who are not completely dependent on parenteral nutrition, but who will experience better quality of life if it is supplementary in some form."

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[54] 20 CFR 404.1525(a) and 416.925(a).
[55] Nightingale, J. & Woodward, J. M. (2006). Guidelines for management of patients with a short bowel. *Gut, 55*(Suppl IV), iv1-iv12. https://doi.10.1136/gut.2006.091108

Response: We did not adopt this comment. The statutory definition of disability concerns a person's ability to do work, not on quality of life.[56] The commenter described alternative, less burdensome, treatment options that assist patients with achieving independence, but these alternatives, on their own, are not indicative of listing-level severity. The listings are designed to identify cases at an early stage of the sequential evaluation process that meet a strict threshold for the statutory definition of disability. They describe impairments that we consider severe enough to prevent an adult from doing any gainful activity.[57] For children, the listings describe impairments we consider severe enough to cause marked and severe functional limitations.[58] If an impairment does not meet a listing, this does not mean that we will deny a claim. If an adult's impairment(s) does not meet or medically equal any listing, we may find that person disabled at a later step in the sequential evaluation process.[59] If a child's impairment(s) does not meet or medically equal any listing, we may find that their impairment(s) functionally equal the listings.[60]

Comment: One commenter suggested we revise the listings for SBS (5.07 and 105.07) or add a new listing to more broadly address intestinal failure with need for parenteral nutrition. They suggested that for children with impaired or absent intestinal motility from an increasing number of congenital and acquired conditions, the same impairments exist without the surgery requirement as with SBS (for example, gastroschisis, omphalocele, long segment Hirschprung's, and increasingly recognized disorders of mitochondria and other cellular functions that severely impair intestinal functioning).

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[56] 42 U.S.C. 416(i) and 423(d).
[57] 20 CFR 404.1525(a) and 416.925(a).
[58] 20 CFR 416.925(a).
[59] 20 CFR 404.1520 and 416.920.
[60] 20 CFR 416.924.

Response: We adopted this comment. Our intent in the proposed expanded listings for SBS was to include individuals whose medical records do not contain documentation of resection of more than one-half of the small intestine, but whose loss of intestinal function is so severe that daily parenteral nutrition is needed to maintain health. Along these lines, the commenters brought a perspective that we had not considered when they suggested the inclusion of other similar intestinal conditions that could cause intestinal failure with the same degree of impairment of gut function, but in the absence of SBS. When we considered these comments, we accepted them, because the research cited in the comments as well as our own supplemental research and review of cases confirmed that other common causes of chronic intestinal failure – specifically, extensive small bowel mucosal disease and chronic motility disorders – can similarly impair intestinal function and prevent absorption of macronutrients or water and electrolytes below that necessary to maintain life, also requiring daily parenteral nutrition.[61,62,63,64,65] Therefore, we expanded and renamed listings 5.07 and 105.07 *Intestinal failure* to cover a greater range of chronic dysmotility or absent motility disorders lasting or expected to last at least 12 months and reducing gut function below the minimum necessary for the absorption of macronutrients or water and electrolytes sufficient for health, as we explain

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[61] Thompson JS, Rochling FA, Weseman RA, Mercer DF. Current management of short bowel syndrome. *Curr Probl Surg* 49:52-115, 2012. https://doi.org/10.1067/j.cpsurg.2011.10.002

[62] Pironi, L., Arends, J., Baxter, J., Bozzetti, F., Peláez, R. B., Cuerda, C., Forbes, A., Gabe, S., Gillanders, L., Holst, M., Jeppesen, P. B., Joly, F., Kelly, D., Klek, S., Irtun, Ø., Olde Damink, S. W., Panisic, M., Rasmussen, H. H., Staun, M., Szczepanek, K., … Acute Intestinal Failure Special Interest Groups of ESPEN (2015). ESPEN endorsed recommendations. Definition and classification of intestinal failure in adults. *Clinical nutrition (Edinburgh, Scotland)*, *34*(2), 171–180. https://doi.org/10.1016/j.clnu.2014.08.017

[63] Pironi, L., Arends, J., Bozzetti, F., Cuerda, C., Gillanders, L., Jeppesen, P. B., Joly, F., Kelly, D., Lal, S., Staun, M., Szczepanek, K., Van Gossum, A., Wanten, G., Schneider, S. M., & Home Artificial Nutrition & Chronic Intestinal Failure Special Interest Group of ESPEN (2016). ESPEN guidelines on chronic intestinal failure in adults. *Clinical nutrition (Edinburgh, Scotland)*, *35*(2), 247–307. https://doi.org/10.1016/j.clnu.2016.01.020

[64] Deutsch, L., Cloutier, A., & Lal, S. (2020). Advances in chronic intestinal failure management and therapies. *Current opinion in gastroenterology*, *36*(3), 223–229. https://doi.org/10.1097/MOG.0000000000000631

[65] Pierret, A., Wilkinson, J. T., Zilbauer, M., & Mann, J. P. (2019). Clinical outcomes in pediatric intestinal failure: a meta-analysis and meta-regression. *The American journal of clinical nutrition*, *110*(2), 430–436. https://doi.org/10.1093/ajcn/nqz110

in the introductory text in 5.00E1 and 105.00E1 (*What is intestinal failure, and how do we evaluate it under 5.07/105.07?*).

Malnutrition

Comment: A number of commenters expressed concern about and suggestions for our proposed criteria for malnutrition in listing 5.08 (*Weight loss due to any digestive disorder*), particularly the use of laboratory values such as hemoglobin or albumin. Commenters also suggested we remove the requirement that malnutrition be caused by a digestive disorder. However, these commenters supported our proposed change to the period over which the criteria must appear in the medical evidence of record for listing 5.08 (*Weight loss due to any digestive disorder*), as well as multiple other digestive listings, from a period of 6 months to a period of 12 months.

Response: We carefully considered all of the concerns raised by the commenters and concluded that we should not finalize our proposed changes to add measurements of hemoglobin and albumin to this listing. Intending to improve the specificity of the listing, we had proposed these biomarkers in congruence with using the term "malnutrition" instead of "weight loss" along with proposing that weight loss be the result of malnutrition caused by a digestive disorder. We reviewed the comments and research supporting the comments[66,67] suggesting that these measurements are not the best indicators of listing-level weight loss in adults and we ultimately agreed with the

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[66] Becker, P., Carney, L. N., Corkins, M. R., Monczka, J., Smith, E., Smith, S. E., Spear, B. A., & White, J. V. (2015). Consensus statement of the Academy of Nutrition and Dietetics/American Society for Parenteral and Enteral Nutrition: Indicators recommended for the identification and documentation of pediatric malnutrition (undernutrition). *Nutrition in Clinical Practice, 30*(1), 147-161. https://doi.org/10.1177/0884533614557642

[67] White, J. V., Guenter, P., Jensen, G., Malone, A., & Schofield, M. (2012). Consensus statement: Academy of Nutrition and Dietetics and American Society for Parenteral and Enteral Nutrition: Characteristics recommended for the identification and documentation of adult malnutrition (undernutrition). *Journal of Parenteral and Enteral Nutrition, 36*(3), 275-283. https://doi.org/10.1177/0148607112440285

commenters that malnutrition caused by a digestive disorder does not have a strong enough relationship with those biomarkers to include them in the listing. That is, these biomarkers are not specific to malnutrition and can instead be indicative of other conditions such as cancers, autoimmune disorders, bleeding, and cardiovascular diseases.[68,69] We concluded that there are not currently biomarkers or other clinical evidence that are both regularly available in medical records and highly specific to severe, listing-level malnutrition. Therefore, after consultation with agency medical experts and reviewing research provided by one of the commenters, we determined that the BMI remains the most specific and readily available documentation of digestive disorders that have caused weight loss so severe that it prevents any gainful activity, and we will retain the current body mass index (BMI) criteria in listing 5.08 (*Weight loss due to any digestive disorder*).

Likewise, consistent with the comments supporting the change from 6 months to 12 months, we kept the proposed revision in the final language for listing 5.08 (*Weight loss due to any digestive disorder*) to require the two BMI calculations to be within a consecutive 12-month period. We made the appropriate related changes to the introductory text, including 5.00A (*Which digestive disorders do we evaluate in this body system?*), 5.00D (*What is inflammatory bowel disease (IBD), and how do we evaluate it under 5.06?*), and 5.00F (*How do we evaluate weight loss due to any digestive disorder under 5.08?*).

Because we are not finalizing our proposal to use laboratory values such as hemoglobin or albumin in listing 5.08, we also retained current 5.06B1 ("Anemia") and 5.06B2 ("Serum albumin"). We proposed to remove them due to redundancy with the

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[68] Gounden, V., Vashisht, R., & Jialal, I. (2021). Hypoalbuminemia. In *StatPearls [Internet]*. StatPearls Publishing. https://www.ncbi.nlm.nih.gov/books/NBK526080/

[69] National Heart Lung and Blood Institute. (2011). *Your guide to anemia* (NIH Publication No. 11-7629). US Department of Health and Human Services, National Institutes of Health. https://www.nhlbi.nih.gov/files/docs/public/blood/anemia-yg.pdf

proposed criteria for 5.08 (*Weight loss due to any digestive disorder)*. We also retained current 5.00E4 and 105.00E4 ("Surgical diversion of the intestinal tract") as 5.00D3 and 105.00D3.

We did not adopt the suggestion to omit the words "due to any digestive disorder" from listing 5.08 because we define digestive disorders in 5.00A (*Which digestive disorders do we evaluate in this body system?*) as disorders "that result in severe dysfunction of the liver, pancreas, and gastrointestinal tract."

Comment: One commenter expressed concern about the proposed change to listings 5.08 (*Weight loss due to any digestive disorder*) and 105.08 (*Growth failure due to any digestive disorder*) from a 6-month period for the two data points (two BMI calculations) to a 12-month period, because of the detrimental effects of malnutrition over time.

Response: We did not adopt the comment, because the commenter's remarks seem to indicate a misunderstanding of our proposal. The commenter seems to believe that the two data points must be taken 12 months apart, but we did not propose a requirement that the two data points be taken 12 months apart. Our proposed requirement, finalized in this final rule, specifies that the two measurements must both be taken during a 12-month period and must be at least 60 days apart from one another during the 12-month period.

Comment: One commenter asked that we consider a higher BMI criterion, such as 20 or 22, for elderly patients under proposed listing 5.08 (*Weight loss due to any digestive disorder*).

Response: We did not adopt this comment. We do not adjust BMI calculations based on an adult person's age.[70] The disability program rules, including the listings, end

[70] Center for Disease Control. https://www.cdc.gov/healthyweight/assessing/bmi/adult_bmi/index.html. The CDC does not alter BMI calculations for adults 20 years and older.

at full retirement age. If the person has not yet reached full retirement age, we will consider age at a later step in the sequential evaluation process, when we consider the person's residual functional capacity, age, education, and work experience.[71]

Comment: One commenter stated that listing 5.08 (*Weight loss due to any digestive disorder*) does not specifically address eating disorders. The commenter asked us to add language to the preamble (listing introductory text) to clarify that adjudicators should utilize listing 12.13 (*Eating disorders*) to address eating disorders in listing 5.08 (*Weight loss due to any digestive disorder*).

Response: We adopted this comment. Listing 5.08 (*Weight loss due to any digestive disorder)* is used to evaluate digestive disorders that result in significant or serious weight loss. We define digestive disorders in 5.00A (*Which digestive disorders do we evaluate in this body system?*) as disorders "that result in severe dysfunction of the liver, pancreas, and gastrointestinal tract." However, severe, listing-level weight loss can occur as a result of impairments other than digestive disorders, such as due to certain genitourinary, immune, or mental disorders. We have added language to the introductory text in 5.00F (*How do we evaluate weight loss due to any digestive disorder under 5.08?*) and 105.00F (*How do we evaluate growth failure due to any digestive disorder under 105.08?*) to provide adjudicators with guidance on how to evaluate weight loss not caused by a digestive disorder. Specifically, we explain that impairments other than digestive disorders that cause weight loss should be evaluated under the appropriate body system for that impairment. If the claimant develops a digestive disorder as the result of another impairment, we will evaluate the acquired digestive disorder under our rules for digestive disorders.

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[71] 20 CFR 404.1520 and 416.920.

Comment: One commenter recommended that malnutrition be included as a causative factor for each of the digestive disorders, because it results in functional impairments.

Response: We did not adopt this comment. We disagree with the commenter's assertion that malnutrition is a causative factor for each of the digestive disorders. For example, while increased malnutrition risk is associated with IBD, it is not thought to cause IBD.[72,73]

Growth Failure

Comment: One commenter suggested that we define growth failure as weight-for-height/length or BMI z-scores less than 2. Another commenter requested that we use z-scores for single data points in listing 105.08 (*Growth failure due to any digestive disorder*). The commenter recommended a z-score of < -1 for weight-for-height, BMI-for-age, length/height for age, or mid-arm muscle circumference defining risk of malnutrition and multiple z-score measurements over time demonstrating a deceleration of weight for length/height diagnosing malnutrition. The commenter also proposed looking at weight gain velocity, weight loss, or inadequate nutrient intake to diagnose malnutrition.

Response: We did not adopt these comments. We did not propose to change the requirements in listing 105.08 (*Growth failure due to any digestive disorder*). Our long-standing policy is to use the third percentile, going back to the inception of listing 105.08 (*Growth failure due to any digestive disorder*) in 1977.[74] As we explained in the 2001

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[72] Schreiner, P., Martinho-Grueber, M., Studerus, D., Vavricka, S. R., Tilg, H., & Biedermann, L. (2020). Nutrition in inflammatory bowel disease. *Digestion, 101*(Suppl. 1), 120-135. https://doi.org/10.1159/000505368

[73] Ramos, G. P., & Papadakis, K. A. (2019). Mechanisms of disease: Inflammatory bowel diseases. *Mayo Clinic Proceedings, 94*(1), 155-165. https://doi.org/10.1016/j.mayocp.2018.09.013

[74] 42 FR 14705, 14710 (1977).

NPRM on which the current criteria are based, "[t]he 3rd percentile is generally accepted as the lower limit of the normal range for most biologic measurements."[75] A child whose weight is in the 3rd percentile weighs the same or more than 3 percent of the reference population, and weighs less than 97 percent of the children in the reference population. Percentiles are commonly used to assess the growth of children in the United States. We are continuing our policy that measurements below the third percentile correspond to listing-level severity for children because the Centers for Disease Control and Prevention (CDC) growth tables continues to provide percentiles.[76] The tables included in 105.08 (*Growth failure due to any digestive disorder*) are equivalent[77] to the CDC growth tables.[78] In the development of these tables, the CDC elected to use the third percentile as approximate to a z-score of -2, which is a standard statistical cutoff point to determine the need for nutritional intervention.[79] The CDC explained that "[p]ercentiles are the most commonly used clinical indicator to assess the size and growth patterns of individual children in the United States."[80] The third percentile on the CDC charts identifies the extremes of the distribution and is referenced by pediatric endocrinologists and others who assess the growth of children with special health care requirements.[81] The childhood listings describe impairments that cause marked and severe functional limitations.[82]

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[75] 66 FR 57009, 57014 (2001).

[76] 66 FR at 57021 (2001).

[77] The values in our table are generally the same as those used by the CDC, but we have rounded to the nearest tenth and grouped same values into a single line on our table. For example: Row 1 on the CDC table for boys age 2 is 14.50347667 and row 2 for boys age 2.1 is 14.46882381. Both of these values round to 14.5, so on the SSA table the value of 14.5 is given for boys age 2-2.1. Furthermore, although the CDC table goes to age 20 for boys, we do not use the values for age 18-20, because we do not use the childhood listings for individuals 18 and older.

[78] National Center for Health Studies. (2002, May). *2000 CDC Growth Charts for the United States: Methods and Development.* United States Department of Health & Human Services https://www.cdc.gov/nchs/data/series/sr_11/sr11_246.pdf.

[79] Id.

[80] Id.

[81] National Center for Health Studies. (2017, June). *Clinical Growth Charts.* Centers for Disease Control and Prevention. https://www.cdc.gov/growthcharts/clinical_charts.htm.

[82] 20 CFR 416.925.

Listing 105.08 (*Growth failure due to any digestive disorder*) specifically describes growth failure due to a digestive disorder (such as malnutrition) that is severe enough to meet this threshold. Listing 105.08 (*Growth failure due to any digestive disorder*) is not intended to provide diagnostic guidelines for such a disorder generally, or to help identify children who may be at risk of a disorder.

Comment: One commenter stated that we did not provide adequate justification for our selection of using the 3rd percentile values for weight-for length and our selection of albumin and hemoglobin levels in listing 105.08 (*Growth failure due to any digestive disorder*).

Response: The comment reflects a misunderstanding since we did not propose to change the requirements in listing 105.08 (*Growth failure due to any digestive disorder*). The text in this section of the listing is unchanged, and identical to our existing regulatory text, but we chose to republish it for the clarity and continuity of the listing as a whole.

Other Digestive Disorders Comments

Comment: One commenter asked if we considered expanding the one-year period for which we consider a person to be under a disability following liver (5.09, 105.09 (*Liver transplantation*)), small intestine (5.11, 105.11 (*Small intestine transplantation*)), or pancreas (5.12, 105.12 (*Pancreas transplantation*)) transplant, because post-transplant follow-up, complications, or adverse effects of immunosuppression may persist for longer than a year.

Response: We considered this comment and are not making any changes. The one-year period of disability following liver, small intestine, or pancreas transplant in these listings is consistent with the listings for heart transplant (4.09 (*Heart transplant*)) and kidney transplant (6.04 (*Chronic kidney disease,* with kidney transplant)). Like other organ transplant recipients, liver transplant recipients are at risk of developing post-

transplant complications such as organ rejection or infection. The risk of rejection is highest during the first 3-6 months after transplantation and then decreases significantly.[83] Bacterial infections are most common within the first month and viral infections generally occur within the first 6 months.[84] Medical literature for liver transplant recipients indicates that most transplant recipients are able to return to activities of daily living and work within 12 months.[85]

We reevaluate the claim at the end of the one-year period, using updated medical records and any other necessary information to determine if there is continuing disability.[86] Additionally, we do not automatically cease benefits once the one-year period has concluded. As we explain in 5.00G and 105.00G (*How do we evaluate digestive organ transplantation?*), after the one-year period, we evaluate the person's post-transplant function, the frequency and severity of any rejection episodes, complications in other body systems, and adverse treatment effects. A continuation or cessation of disability depends on the evidence found in the medical record at the time of reevaluation.[87]

Comment: One commenter suggested that we revise listing 105.10 (*Need for supplemental daily enteral feeding via a gastrostomy*) "to include tube feeding by nasogastric or nasojejunal tube feeding, or gastrojejunostomy, as well as by gastrostomy."

Response: We partially adopted this comment. We revised listing 105.10 (*Need for supplemental daily enteral feeding via a gastrostomy*) to include tube feeding by

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[83] Manzarbeitia, C., & Arvelakis, A. (2019, January 11). *Liver transplantation treatment & management*. Medscape. https://emedicine.medscape.com/article/431783-treatment

[84] Roayaie, K., & Feng, S. *Liver transplant*. University of California San Francisco Transplant Surgery Department of Surgery. https://transplantsurgery.ucsf.edu/conditions--procedures/liver-transplant.aspx

[85] Mayo Clinic Staff. (2020, July 15). *Liver transplant*. Mayo Clinic. https://www.mayoclinic.org/tests-procedures/liver-transplant/about/pac-20384842

[86] See 5.00G and 105.00G (*How do we evaluate digestive organ transplantation?*).

[87] 20 CFR 404.1589 and 416.989.

jejunostomy or duodenostomy, as well as by gastrostomy. We did not include nasogastric or nasojejunal tube feeding. Nasogastric or nasojejunal tube feeding methods are likely to be used for relatively short periods of time and would not meet the durational requirement for disability.[88,89] We also updated the introductory text at 105.00H (*How do we evaluate the need for supplemental daily enteral feeding via a gastrostomy, duodenostomy, or jejunostomy?*) to reflect this additional language.

Comment: One commenter asked that we "clarify how pancreatic disease would be identified since it is not included as a separate listing."

Response: We did not make any changes to this rule based on this comment. We do not have a listing for every digestive disorder. However, we evaluate unlisted digestive disorders under the sequential evaluation process, as we explain in 5.00J and 105.00L (*How do we evaluate digestive disorders that do not meet one of these listings?*). We will first consider whether an impairment, such as pancreatic disease, medically equals a listing. If the impairment(s) does not medically equal the criteria of a listing, this does not mean that we will deny the claim. If an adult's impairment(s) does not meet or medically equal any listing, we may find that person disabled at a later step in the sequential evaluation process.[90] If a child's impairment(s) does not meet or medically equal any listing, we may find that their impairment(s) functionally equal the listings.[91]

Comment: Several commenters asked us to add that a lack of opioid or narcotic prescriptions or attempts to reduce or avoid use of such medication should never be considered indicative of the severity of an impairment, nor should it affect an adjudicator's decision about whether an impairment can reasonably be expected to

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[88]Yi, D. Y. (2018). Enteral nutrition in pediatric patients. *Pediatric Gastroenterology, Hepatology, & Nutrition, 21*(1), 12-19. https://doi.org/10.5223/pghn.2018.21.1.12

[89] 20 CFR 416.906 and 416.909.

[90] 20 CFR 404.1520 and 416.920

[91] 20 CFR 416.924

produce a person's symptoms (including pain) or about the intensity and severity of such symptoms.

Response: We did not adopt these comments. The disability program rules require the presence of a medically determinable impairment that can reasonably be expected to produce the symptoms (including pain). Our adjudicators consider all evidence in the record when making this finding, including a description of the person's medications and the effects of those medications on the allegations of pain, as well as factors such as the person's daily activities, the location, duration, frequency, and intensity of their symptoms, treatment other than medication, and any measures other than treatment that the person uses to alleviate their symptoms, such as the need to change positions.[92] If a person is prescribed any medication, including opioid or other narcotic medication, and chooses to not take the medication, we use our rules regarding the need to follow prescribed treatment, which apply to all medical conditions, not just digestive disorders, and are explained in 20 CFR 404.1530 and 416.930 (*Need to follow prescribed treatment*). In conjunction with our regulations, we provide additional guidance on following prescribed treatment in SSR 18-3p (*Titles II and XVI: Failure to Follow Prescribed Treatment)*, in which we include the "risk of addiction to opioid medication" as an example of a "good cause" reason for not following prescribed treatment."[93] As such, it is already our policy that a lack of, or reduction of, opioid or narcotic prescriptions due to the risk of addiction will not adversely affect a person's claim during the adjudication process. Consequently, there is no need to specify such within this specific medical listing.

Comment: One commenter stated that we failed to provide evidence that we considered the tolerance of employers when dealing with the issues associated with

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[92] 20 CFR 404.1529(c)(3), 416.929(c)(3), and Social Security Ruling (SSR) 16-3p (2016). Available at: https://www.ssa.gov/OP_Home/rulings/di/01/SSR2016-03-di-01.html

[93] SSR 18-3p (2018). Available at: https://www.ssa.gov/OP_Home/rulings/di/02/SSR2018-03-di-02.html

digestive disorders (for example, diarrhea, fecal incontinence, rectal bleeding, abdominal pain, fatigue, fever, nausea, vomiting, and arthralgia).

Response: We did not make changes in response to the comment, because we follow our statutory requirements. The Act states a person shall be determined to be under a disability only if the person is unable to do any substantial gainful activity, regardless of whether an employer would hire them.[94] The listings, however, identify impairments we consider severe enough to prevent a person from doing *any gainful activity*, regardless of the person's age, education, or work experience.[95] Consistent with the Act, we do not consider whether employers may be unwilling to hire a person with a particular impairment, such as a digestive disorder. Individual, employer-specific policies vary in scope and so are not appropriate for our national program, which uses a definition of disability that can be uniformly applied throughout the nation. We will consider the effects of an individual's resulting symptoms from their medically determinable digestive disorders, such as those identified by the commenter when we assess and consider the individual's residual functional capacity at later steps in our sequential evaluation process.[96]

Skin Disorders

Comment: Several commenters asked that we add wheeled mobility devices, specifically wheelchairs, adaptive or special needs strollers, and scooters, to our definition of "assistive device(s)" in 8.00B1 and 108.00B1 (*Assistive device(s)*).[97] The commenters also noted that while the wheeled mobility devices they requested are not hand-held or worn, they improve stability and mobility, and stated claimants with a

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[94] 42 U.S.C. 423(d)(2)(A) and 42 U.S.C. 1382c(a)(3)(B).

[95] 20 CFR 404.1525 and 20 CFR 416.925.

[96] 20 CFR 404.1520 and 20 CFR 416.920.

[97] We note that the commenters referenced 8.00B2 and 108.00B2 (*Chronic skin lesions*), which is not correct. The correct reference for the definition of "assistive device(s)" for this comment is 8.00B1 and 108.00B1 (*Assistive device(s)*).

documented medical need for these devices have functional limitations at least as significant to those with a need for other assistive devices.

Response: We generally adopted these comments, specifying alternative examples. We incorporated devices used in a seated position into the definition of assistive device(s) in 8.00B1 and 108.00B1 (*Assistive device(s)*). Rather than using the suggested examples of "wheelchairs, adaptive or special needs strollers, and scooters," we used examples such as wheelchair, rollator, and power operated vehicle. We chose these examples because the National Academies of Sciences, Engineering, and Medicine described these types of wheeled and seated mobility devices in a consensus study report on assistive technology.[98] This change is also consistent with the definition of "assistive device(s)" used in the recently published final rule, *Revised Medical Criteria for Evaluating Musculoskeletal Disorders*.[99]

Comment: Several commenters stated that the definition of "fine and gross movements" in 8.00B5 and 108.00B5 (*Fine and gross movements*) should include "feeling" as a fine movement, in keeping with SSR 85-15 (*Titles II and XVI: Capability to Do Other Work – The Medical-Vocational Rules as a Framework for Evaluating Solely Nonexertional Impairments*.)[100] In addition, a commenter also referenced SSR 09-6p (*Title XVI: Determining Childhood Disability – The Functional Equivalence Domain of "Moving About and Manipulating Objects."*)[101]

Response: We disagree with the comments and did not adopt the suggestion. SSR 85-15 (*Titles II and XVI: Capability to Do Other Work – The Medical-Vocational Rules as a Framework for Evaluating Solely Nonexertional Impairments*) provides guidance to

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[98] National Academies of Sciences, Engineering, and Medicine. (2017). *The promise of assistive technology to enhance activity and work participation*. The National Academies Press. https://doi.org/10.17226/24740

[99] 85 FR 78164 (2020).

[100] SSR 85-15 (1985). Available at: https://www.ssa.gov/OP_Home/rulings/di/02/SSR85-15-di-02.html

[101] SSR 09-6p (2009). Available at: https://www.ssa.gov/OP_Home/rulings/ssi/02/SSR2009-06-ssi-02.html

our adjudicators on the capability to do other work, applicable at step 5 of the sequential evaluation process; it is therefore not within the scope of this final rule, which addresses the listings step of the sequential evaluation process. With regard to SSR 09-6p (*Title XVI: Determining Childhood Disability – The Functional Equivalence Domain of "Moving About and Manipulating Objects"*), this SSR is consolidated guidance for our adjudicators for evaluating the functional equivalence domain of moving about and manipulating objects for children, which is also not within the scope of this final rule. While these SSRs are not within the scope of this final rule, we note that SSR 09-6p (*Title XVI: Determining Childhood Disability – The Functional Equivalence Domain of "Moving About and Manipulating Objects"*) does not specifically mention feeling in regard to fine and gross movements, only that sensory loss that interferes with motor activities is a limitation we consider under the domain of "moving about and manipulating objects." Moreover, SSR 85-15 (*Titles II and XVI: Capability to Do Other Work – The Medical-Vocational Rules as a Framework for Evaluating Solely Nonexertional Impairments*) discusses "feeling" as a manipulative impairment, not as a fine movement as the commenter implies. However, if the claimant's skin condition causes limitations in their ability to feel, which also results in significant deficits in their ability to perform fine and gross movements as defined in 8.00B5 and 108.00B5 (*Fine and gross movements*), their skin condition may be found to meet the listing criteria. If the evidence does not support a finding that the claimant's skin condition meets a listing, any additional impact of the claimant's loss of ability to feel due to a skin condition would be evaluated under our medical equivalence rules (as well as our functional equivalence rules for child claimants) at step 3 of the sequential evaluation, or at steps 4 and 5 of the sequential evaluation process for adult claimants.[102]

[102] 20 CFR 404.1545(d) and 416.945(d)

Comment: Several commenters stated that it was unclear why proposed sections 8.00C3d and 108.00C3d (*What evidence do we need to evaluate your skin disorder?*) require information about the claimant's "history of familial incidence" of a skin impairment.[103] They asserted that the information may be unobtainable (for example, family members may be absent, deceased, not receiving medical treatment, or reluctant to share medical information), and the history does not affect the claimant's level of functioning.

Response: Our changes only reorganized the current guidance into an outline format for easier reading; we did not propose new requirements. Additionally, our guidance in 8.00B and 108.08B (*What documentation do we need?*) applies to the entirety of the skin listings, and as we state in 8.00A and 108.00A (*Which skin disorders do we evaluate under these listings?*) of the current rules, we evaluate skin disorders that result from hereditary, congenital, or acquired pathological processes. Therefore, a history of familial incidence, when available, may help us in evaluating hereditary skin disorders. For example, for many inherited skin disorders, we consider a family history as key information in helping establish a medically determinable impairment.[104] Additionally, other conditions, such as atopic dermatitis, have a high familial occurrence, and therefore a family history is useful information in establishing the presence of a medically determinable impairment.[105] However, for other skin conditions, including acquired conditions such as burn injuries, a familial history is less relevant, and we would not seek information on familial incidence in those cases. Nevertheless, we made minor changes in response to this comment, and acknowledge some claimants will not have a

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[103] 84 FR at 35948, 35956 (2019).

[104] Tantcheva-Poor, I., Oji, V., & Has, C. (2016) A multistep approach to the diagnosis of rare genodermatoses. *Journal of the German Society of Dermatology, 14*(10), 969-986. https://doi.org/10.1111/ddg.13140

[105] DeStefano, G. M., & Christiano, A. M. (2014) The genetics of human skin disease. *Cold Spring Harbor Perspectives in Medicine, 4*(10), a015172. https://doi.org/10.1101/cshperspect.a015172

history of familial incidence or access to adequate or any health information about genetic relatives. While familial incidence is useful, we will use other available information and medical evidence to establish the medically determinable impairment in instances where it is not available.

We modified 8.00C3 and 108.00C3 (*What evidence do we need to evaluate your skin disorder*?) and its subparagraphs. In this final rule, we split the requirements from proposed 8.00C3d and 108.00C3d ("Your history of familial incidence; exposure to toxins, allergens or irritants; seasonal variations; and stress factors") into two paragraphs, and we revised our wording about history of familial incidence to "Any available history of familial incidence" in final 8.00C3d and 108.00C3d ("Any available history of familial incidence"). We inserted "Your exposure to toxins, allergens, or irritants; seasonal variations; and stress factors" into final 8.00C3e ("Your exposure to toxins, allergens or irritants; seasonal variations; and stress factors") and 108.00C3e ("Your exposure to toxins, allergens or irritants; seasonal variations; and stress factors").

We relettered subparagraphs 8.00C3e and 108.00C3e ("Your ability to function outside of a highly protective environment") through 8.00C3h and 108.00C3h ("Statements you or others make about your disorder(s), your restrictions, and your daily activities") to 8.00C3f through 8.00C3i and 108.00C3f through 108.00C3i, respectively.

Comment: Several commenters asked that we omit the word "prescribed" from 8.00D (*How do we evaluate the severity of skin disorders?*) because some medically necessary treatments recommended by medical providers for skin conditions (for example, medicated baths, frequent bandage changes, or over-the-counter ointments) do not require a prescription. The commenters believe that this change would better align with the statement in 8.00B4 (*Documented medical need*) that assistive devices do not need to be prescribed in order to be considered by adjudicators.

Response: We have partially accepted this comment. As the commenters note, and as is consistent with our other regulations, medical providers other than physicians may "prescribe" or recommend treatment. To acknowledge this, we are changing the term "physician" in 8.00D5b and 108.00d5b (*Despite adherence to prescribed medical treatment for 3 months*) to "medical source" to account for the types of treatments identified by the commenters above.[106] As defined in our regulations, a "medical source" means an individual who is licensed as a healthcare worker by a State and working within the scope of practice permitted under State or Federal law, or an individual who is certified by a State as a speech-language pathologist or a school psychologist and acting within the scope of practice permitted under State or Federal law.[107] Prescribed medical treatment means that a medical source has instructed the patient to adhere to a specified treatment, such as any medication, surgery, therapy, the use of durable medical equipment, or the use of assistive devices. Prescribed treatment does not include lifestyle modifications, such as dieting, exercise, or smoking cessation. We will consider any evidence of prescribed treatment, whether it appears on prescription forms or is otherwise indicated within a medical source's records. An assistive device(s), as explained in 8.00B and 108.00B (*What are our definitions for the following terms used in this body system?*) of this final rule, is not a treatment method for a skin disorder. An assistive device(s) is any device used to improve stability, dexterity, or mobility, and does not need to be prescribed for adjudicators to consider its use as long as there is a documented medical need for the assistive device.

Comment: A few commenters stated that proposed 8.00D6b ("If, for any reason, you have not received treatment")[108] is contrary to the "spirit" of SSR 18-3p (*Titles II and*

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[106] 20 CFR 404.1502(d) and 416.902(i).

[107] Id.

[108] Paragraph 8.00D6b ("If, for any reason, you have not received treatment") of the proposed and final rule states in part, "If, for any reason, you have not received treatment, your skin disorder cannot meet the criteria for 8.09."

XVI: Failure to Follow Prescribed Treatment).[109] The commenters added that SSR 18-3p provides "several reasons (including religion, inability to pay, incapacity, intense fear of surgery, risk of opioid addiction, etc.) why noncompliance with prescribed medicine could be excused." The commenters state that the same exceptions for excusing medical treatment compliance might be the same reasons why a person has not received treatment. The commenters recommended that if we do not remove proposed 8.00D6b ("If, for any reason, you have not received treatment"), we should state that the reasons from SSR 18-3p are reasons a skin disorder could meet listing 8.09 (*Chronic conditions of the skin or mucous membranes*) without evidence of treatment.

Response: We did not adopt these comments. The commenters misunderstand our policy for failure to follow prescribed treatment in this instance. We only consider our failure to follow prescribed treatment policy and procedures after determining that a person is entitled to disability benefits. Once we determine that a person is entitled to disability benefits, we determine whether the evidence indicates that the person might not have been entitled to disability benefits if they had followed prescribed treatment. Therefore, in the case of listing 8.09 (*Chronic conditions of the skin or mucous membranes*), before we make a failure to follow prescribed treatment determination, we first need to determine that a person's skin disorder meets all of our criteria for listing 8.09 (*Chronic conditions of the skin or mucous membranes*), including listing criteria related to treatment. In the introductory text at 8.00D5b (*Despite adherence to prescribed medical treatment for 3 months*) we state that under listing 8.09 (*Chronic conditions of the skin or mucous membranes*), we require that a person's symptoms persist "despite adherence to prescribed treatment for 3 months." The adherence to prescribed treatment is a part of the listing criteria and must be present in order for a person's skin condition to

[109] 83 FR 49616 (2018) and SSR 18-3p (2018). Available at: https://www.ssa.gov/OP_Home/rulings/di/02/SSR2018-03-di-02.html

meet the criteria of the listing. Therefore, it is not possible to find a person disabled under listing 8.09 (*Chronic conditions of the skin or mucous membranes*) without a record of prescribed treatment, which is further explained in paragraph 8.00D6b ("If, for any reason, you have not received treatment"). This is clarified by our guidance in SSR 18-3p (*Titles II and XVI: Failure to Follow Prescribed Treatment*), where we explain that a failure to follow prescribed treatment determination is not applicable when a listed impairment(s) requires us to consider whether a person was following a specific treatment as part of satisfying the listing analysis.

Moreover, the requirement for prescribed treatment for skin disorders dates back to 1979.[110] We last comprehensively revised the listings for evaluating skin disorders in 2004. In the preamble to that final rule, we explained that the original requirement for extensive lesions "not responding to prescribed treatment" was replaced with the more specific requirement that there be "extensive skin lesions that persist for at least 3 months despite continuing treatment as prescribed."[111] We are retaining that requirement with this update; however, with this final rule, we are finalizing our proposal to change the language to "despite adherence to prescribed medical treatment" to be more consistent with current medical terminology.

Additionally, we do not deny a claim if a person does not have an impairment that meets a listing. We may find the impairment(s) medically equals a listing (or, in the case of a child seeking Supplemental Security Income (SSI) payments, functionally equals the listings). If an adult claimant's impairment(s) does not meet or medically equal any listing, we may find them disabled at a later step in the sequential evaluation process. A lack of treatment history, as a solitary factor, does not require us to deny a claim. We

[110] 44 FR 18170, 18187 (1979).
[111] 69 FR 32260, 32264 (2004).

evaluate a claim, including all record evidence, regardless of whether a person has received treatment for their impairment(s).

Comment: Several commenters asked us not to finalize the proposed changes to the functional criteria because the changes we propose to the skin disorders listings are "more onerous," and they assert that fewer applicants will qualify for disability based on these updated criteria. These commenters believed the updates would prolong the process of applying for disability by necessitating assessment at later steps in the sequential evaluation process and would require vocational information and consideration of a person's age, education, and work experience, to make a determination. The commenters also expressed concern that these updates will ultimately result in more denials of claims at the initial and reconsideration levels. For instance, the commenters suggested that a person's skin disorder would be unable to meet a skin disorders listing if only one side of a groin and an axilla (underarm) was involved instead of both sides of the groin or the axillae (underarms).

Response: We did not adopt these comments. The requirement that the claimant's skin disorder results in significant functional limitations lasting a minimum of 12 months despite adherence to treatment dates back to 1979.[112] The introductory text to our 1979 final rule stated that the claimant's skin lesions "must be shown to have persisted for a sufficient period of time despite therapy for a reasonable presumption to be made that severe impairment will last for a continuous period of at least 12 months."[113] This is a requirement in our current rule as well, which states that we require evidence that the claimant's skin disorder results in a degree of functional limitation such that the claimant is "unable to do any gainful activity for a continuous period of at least 12 months" (see current 8.00C2 and 108.00C2 (*Frequency of flare-ups*)). The language in the final rule

[112] 44 FR 18170, 18187 (1979), 45 FR 55566, 55607 (1980), and 50 FR 50068, 50098 (1985).
[113] 44 FR at 18787.

reflects a continuation of this requirement, stating that we must have medically documented evidence of physical limitation(s) of functioning related to the claimant's skin disorder, and that the decrease in physical function resulting from the claimant's skin disorder must have lasted, or can be expected to last, for a continuous period of at least 12 months (8.00D2 and 108.00D2 (*Limitation(s) of physical functioning due to skin disorders*). Further, this is consistent with our program-wide rules for the Listing of Impairments, which identify impairments that preclude the ability to perform any gainful activity (or, in the case of a child applying for SSI payments based on disability, which identify impairments that result in marked and severe functional limitations) and have lasted or can be expected to last for a continuous period of at least 12 months.[114]

Also consistent with our rules dating back to 1979, our current rule acknowledges that because skin disorders frequently respond to treatment, we must have evidence of treatment for a "sufficient time" before we can appropriately assess the impact of the treatment and the resultant effects on the claimant's functional capacity (see current 8.00C4 and 108.00C4 (*Treatment*)). For current adult listings 8.02 (*Ichthyosis*) through 8.06 (*Hidradenitis suppurativa*) and the equivalent current childhood listings 108.02 through 108.06, which have been consolidated into listings 8.09 and 108.09 (*Chronic conditions of the skin or mucous membranes*) in this final rule, the claimant must adhere to prescribed medical treatment for at least three months. The continued presence of the skin disorder despite adherence to prescribed medical treatment for at least three months allows the adjudicator to make a reasonable presumption that the skin disorder will meet the durational requirement for disability.[115] However, medical evidence only showing the continued presence of a skin disorder despite adherence to prescribed treatment is insufficient to find that the claimant's skin disorder meets the listing criteria. In order to

[114] 20 CFR 404.1525 and 416.925.
[115] 20 CFR 404.1509 and 416.909.

find that the claimant's skin impairment meets a listing, we must have evidence of listing-level functional limitation that has lasted, or can be expected to last, for a continuous period of at least 12 months.

Addressing the commenters' concern that our new functional criteria are more onerous, we specifically refer to certain areas of the body in the current and in this final rule. Generally, skin disorders that affect these areas, such as ichthyosis and bulbous diseases, result in functional limitations. This is not a change from our current criteria. In our current criteria at 8.00C1 and 108.00C1 (*Extensive skin lesions*), we define "extensive skin lesions," which we require in current adult listings 8.02 (*Ichthyosis*) through 8.06 (*Hidradenitis suppurativa*) and current childhood listings 108.02 (*Ichthyosis*) through 108.06 (*Hidradenitis suppurativa*), 8.07B and 108.07B ("Other genetic photosensitivity disorders"), and 8.08 and 108.08 (*Burns*), as lesions that "involve multiple body sites or critical body areas, and result in a very serious limitation." We provide examples of "extensive skin lesions," to include conditions such as "skin lesions that interfere with the motion of your joints and that very seriously limit your use of more than one extremity," "skin lesions on the palms of both hands that very seriously limit your ability to do fine and gross motor movements," and "skin lesions on the soles of both feet, the perineum, or both inguinal areas that very seriously limit your ability to ambulate."

The updated functional criteria for skin disorders reflect our continued focus on the functional limitations skin disorders may cause and reflect a level of functional limitation similar to the criteria in our current rules. In order to clarify that focus, we have moved from providing examples of listing-level limitations caused by skin disorders, as we do in the current introductory text, to the use of precise and functional criteria set forth in this final rule at 8.00D2 and 108.00D2 (*Limitation(s) of physical functioning due to skin disorders*). The articulation of these specific functional criteria prompts

adjudicators to focus on the resultant functional limitations caused by the claimant's skin impairment in a consistent manner across cases. In the proposed rule, and in this final rule, we specify that a medically determinable skin impairment will generally meet a listing when it has or can be expected to last for a continuous period of at least 12 months and is medically documented by one of the functional limitations in these listings. This means that the updated rule will not necessarily result in a denial. To use the example cited by the commenter, a person's skin impairment resulting in lesions on an axilla and one side of the groin may still meet one of these listings, because there may be medical documentation that the chronic skin lesions or contractures result in limitations that satisfy at least one of the functional criteria provided.

If an adult's impairment(s) does not meet or medically equal any listing, we may find that person disabled at a later step in the sequential evaluation process.[116] If a child's impairment(s) does not meet or medically equal any listing, we may find that their impairment(s) functionally equal the listings.[117]

Comment: A few commenters asked us to remove the words "third-degree" from proposed 8.08 and 108.08 (*Burns*). The commenters stated that fourth-degree burns, which go beyond the skin and underlying tissue to muscles and bones, are at least as detrimental to functioning as third-degree burns, and that second-degree burns, especially, but not only in combination with higher-degree burns, can cause scarring that causes pain and limits function.

Response: We adopted this comment and removed the qualifier "third-degree" from listings 8.08 and 108.08 (*Burns*). The comment brought a perspective that we hadn't considered. We adopted the comment and removed the qualifier "third degree" from listing 8.08 and 108.08 because skin lesions and contractures that affect function,

[116] 20 CFR 404.1520 and 416.920
[117] 20 CFR 416.924

although often caused by third-degree burns, can also be caused by deep partial thickness (deep second degree) burns or fourth-degree burns.[118] Additionally, the measurement of burn depth in the medical record is not always precise because many providers have difficulty accurately assessing burn depth, there is a need for development of adequate methods of precisely measuring burn depth, and burns often progress to a greater depth than initially documented. [119, 120, 121, 122]

Comment: One commenter asked us to reorder the proposed listings in a more manageable and understandable fashion. Specifically, the commenter stated that by eliminating listings 8.02 (*Ichthyosis*) through 8.09 (*Chronic conditions of the skin or mucous membranes*) and 108.02 (*Ichthyosis*) through 108.09 (*Chronic conditions of the skin or mucous membranes*) we made these listings more complicated to read and administer. The commenter stated that for the relatively unusual skin conditions, cross-referencing and placing all of the examples of skin conditions in the current listings into proposed listings 8.09 and 108.09 (*Chronic conditions of the skin or mucous membranes*) made these listings confusing for adjudicators, advocates, and lay people.

Response: We have partially adopted these comments. We did not adopt the commenter's suggestion to reorder the skin disorders listings; contrary to the commenter's assertion, we did not eliminate listings 8.09 and 108.09 (*Chronic conditions of the skin and mucous membranes*). These are new listings in the proposed rule.

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[118] Jeschke, M. G., van Baar, M. E., Choudhry, M. A., Chung, K. K., Gibran, N. S., & Logsetty, S. (2020). Burn injury. *Nature reviews. Disease primers*, *6*(1), 11. https://doi.org/10.1038/s41572-020-0145-5

[119] Id.

[120] Bettencourt, A. P., Romanowski, K. S., Joe, V., Jeng, J., Carter, J. E., Cartotto, R., Craig, C. K., Fabia, R., Vercruysse, G. A., Hickerson, W. L., Liu, Y., Ryan, C. M., & Schulz, J. T. (2020). Updating the Burn Center Referral Criteria: Results From the 2018 eDelphi Consensus Study. *Journal of burn care & research : official publication of the American Burn Association*, *41*(5), 1052–1062. https://doi.org/10.1093/jbcr/iraa038

[121] Burgess, M., Valdera, F., Varon, D., Kankuri, E., & Nuutila, K. (2022). The Immune and Regenerative Response to Burn Injury. *Cells*, *11*(19), 3073. https://doi.org/10.3390/cells11193073

[122] Markiewicz-Gospodarek, A., Kozioł, M., Tobiasz, M., Baj, J., Radzikowska-Büchner, E., & Przekora, A. (2022). Burn Wound Healing: Clinical Complications, Medical Care, Treatment, and Dressing Types: The Current State of Knowledge for Clinical Practice. *International journal of environmental research and public health*, *19*(3), 1338. https://doi.org/10.3390/ijerph19031338

Similarly, we did not eliminate listings 8.02 (*Ichthyosis*) through 8.08 (*Burns*) and 108.02 (*Ichthyosis*) through 108.08 (*Burns*). Rather, we removed adult listings 8.02 (*Ichthyosis*) through 8.06 (*Hidradenitis suppurativa*) and childhood listings 108.02 (*Ichthyosis*) through 108.06 (*Hidradenitis suppurativa*), and consolidated their current repetitive criteria into one listing for chronic conditions of the skin or mucous membranes (revised 8.09 and 108.09 (*Chronic conditions of the skin and mucous membranes*)), regardless of whether the condition is commonly known or relatively rare, to strengthen adjudicative ease and more efficiently identify adults and children with skin disorders of listing-level severity. As we explained in the NPRM, the criteria in the current listings are identical for each type of skin disorder, and all of the named disorders are chronic conditions of the skin or mucous membranes.[123] For instance, adjudicators will not need to search examples of skin conditions in various skin disorders listings to locate a person's listed medically determinable skin impairment. If "relatively unusual skin conditions" are not in the listed examples of skin disorders, the adjudicator will no longer need to determine which listed impairment(s) is most comparable to a person's medically determinable impairment of the skin or mucous membranes to proceed with evaluating the claim.

As for the commenter's assertion that the revised skin listings are confusing and more complicated to read, we addressed the commenter's concerns by revising the language in 8.07B2 and 108.07B2 ("Chronic skin lesions or contractures"), 8.08 and 108.08 (*Burns*), and 8.09 and 108.09 (*Chronic conditions of the skin or mucous membranes*), to improve the clarity and readability of these listings. Specifically, we removed repetitive language related to impairment-related limitations. In addition to revising the language in these listings to make the criteria easier to understand and apply, we moved the 8.00D2 and 108.00D2 (*Limitation(s) of physical functioning due to skin disorders*) cross references from 8.09A to 8.09B and from 108.09A to 108.09B,

[123] 84 FR 35936 (2019).

respectively, to align with the terms they describe. We did not make any other changes to the cross references. Regarding the use of cross references in revised listing 8.09 (*Chronic conditions of the skin or mucous membranes*), we use cross references throughout the listings for body systems to assist adjudicators, advocates, and lay people with understanding and locating terms and phrases specific to the evaluation of certain listing criteria. We also use cross references to assist readers with recalling other listings or rules that affect how we evaluate specific impairments.

Comment: One commenter asked that we not replace the plain language term "flare-ups" with the medical term "exacerbations."

Response: We did not adopt the suggestion to remove the term "exacerbations," but we did add language to reflect the commenter's request to see "flare-ups" reflected as well. In the final rule, we clarified the definition of the term "exacerbation."[124] We must use appropriate, modern medical terminology to specify the medical criteria we use to evaluate skin disorders, and our research indicates that "exacerbation" is the preferred term among professionals in the field of dermatology.[125] Additionally, we use the term "exacerbation" and not "flare-up" throughout the rules for numerous body systems, so adding the word in the listing for skin disorders will allow for consistency across the multiple body systems.[126] In this final rule, we added a definition to 8.00B and 108.00B (*What are our definitions for the following terms used in this body system?*) based on the

[124] Paragraphs 8.00B7 and 108.00B7 (*Exacerbation*) of the final rule define exacerbation as "an increase in the signs or symptoms of the skin disorder."

[125] A review of the website for the Journal of the American Medical Association (JAMA), a peer-reviewed medical journal published 48 times a year by the American Medical Association, found that the term "exacerbation" was used more than twice as often as the term "flare-up."

[126] We use the term "exacerbations" throughout our respiratory listings (3.00E2, 3.00J, 3.02D, 3.03B, 3.04B, 3.04G, and 3.07, as well as their childhood equivalents), in our current and revised digestive listings (5.00E and 105.00E in the current rules and 5.00D and 105.00D in the revised rule), as well as in the hematological (7.00G), neurological (11.00G, 11.00N1, and 111.00O), mental (12.00F4, 12.00G, 112.00F4, and 112.00G), and the immune listings (14.00I and 114.00I). We do not use the term "flare-up" in any other body system.

medical definition for "exacerbation";[127] however, we also mentioned alternative terms such as "flare" and "flare-up," to reflect the commenter's desire to see the historical term "flare-up" in the listing.

Comment: One commenter stated that many of the terms used in these rules are not defined well enough for adjudicators and the public. The commenter provided the examples of "inability," "maintain an upright position," "fine and gross motor movements," "picking," "pinching," "manipulating and fingering," "handling," "gripping and grasping," "holding," "turning," "reaching," "lifting and carrying," "seriously," "marked," and "prescribed treatment."

Response: We disagree with this comment. This rule uses "fine and gross movements" (not "fine and gross motor movements"), which is a term defined in 8.00B5 and 108.00B5 (*Fine and gross movements*). The majority of the terms identified by this commenter are examples of fine movements[128] and gross movements.[129] We use these terms, as well as "inability," "maintain," "upright position," "prescribed," and "treatment" in this rule as they are defined in common English usage. As we explained in the NPRM, we replaced the current term "continuing treatment as prescribed" with "adherence to prescribed medical treatment" to be consistent with current medical terminology. We changed "prescribed treatment" in 8.00D2 and 108.00D2 (*Limitation(s) of physical functioning due to skin disorders*) to "prescribed medical treatment" to be consistent with current medical terminology. Further, throughout this rule we provide numerous examples of what we will consider as "marked" limitation(s).

Other Comments

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[127] Taber's Cyclopedic Medical Dictionary - 23rd Ed. (2017).

[128] Fine movement examples include picking, pinching, manipulating, and fingering.

[129] Gross movement examples include handling, gripping, grasping, holding, turning, lifting, and carrying.

Comment: One commenter expressed concern that we do not provide quantitative data to show the "validity" of these listings and noted that many people engage in work even though their impairments meet the listing requirements. The commenter opined that this "challenges the credibility" of using the listings to determine whether a person is disabled, and that the listings conflict with the statutory definition of disability. Several other commenters expressed concern that we do not provide any justification for making what they characterize as substantial changes.

Response: We did not make any changes in this final rule based on these comments. Contrary to the commenters' assertion, we provided justification and sources for our changes. In the NPRM, we included an extensive list of references that we relied on in proposing this rule.[130] We also invited the public to comment on these references and the data contained within them. The listings help ensure that determinations and decisions of disability have a sound medical basis, that claimants receive equal treatment throughout the country, and that we can readily identify a significant number of people who meet our definition of disabled. The level of severity described in the listings is such that we consider a person who is not engaging in SGA, and who has an impairment that meets or medically equals all of the criteria of the listing, to generally be unable to do any gainful activity because of the medical impairment alone at step 3 of the sequential evaluation process. When such impairment or combination of impairments meets or medically equals the level of severity described in the listing for the required duration, we will find the person disabled on the basis of medical facts alone in the absence of evidence to the contrary (for example, the actual performance of SGA).

Comment: Two commenters opined that our proposed revisions discriminate against the poor because the criteria in the listings depend on specific diagnoses that, in turn, require medical tests that many people cannot afford and that we will not purchase.

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[130] 84 FR 35936 (2019).

The commenters noted that these tests are not specifically required by the listings, but that they still help establish disability for those people who are able to afford them.

Response: We did not make any changes in this final rule based on these comments. The Act and our regulations require a claimant to submit medical evidence to establish a medically determinable impairment. We use medical evidence generally accepted in the medical community and available in medical records to establish and determine the severity of an impairment. We consider all available evidence about a claimant's impairments, not just information about a particular allegation, such as a skin or digestive condition. If we determine a medical source cannot or will not give us sufficient medical evidence about a person's impairment for us to determine whether a person is disabled, we may also purchase medical examinations or tests to obtain the evidence that we need.[131] We can also find a person disabled even if they do not have a medical diagnosis for their impairment(s) when applying for benefits, as long as we are able to establish a medically determinable severe physical or mental impairment or combination of impairments that meets the duration requirements.

Comment: One commenter stated that the number of combinations of disorders from different body systems far exceeds the number of disorders in any single body system. For example, if there are 100 different digestive disorders and 100 different skin disorders, there are 10,000 combinations of digestive and skin disorders. The commenter added that our proposed listings only include single disorders and leave out many important combinations of disorders. The commenter stated that we have only covered a tiny fraction of the possible disorders two at a time. The commenter alleged that proposed listings discriminate in favor of those with severe single body system disorders and against those with combinations of disorders.

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[131] 20 CFR 404.1517, 404.1519, 404.1519a-404.1519f, 404.1519k, 416.917, 416.919, 416.919a-419.919f, and 416.919k.

Response: We did not adopt this comment. We recognize that digestive disorders and skin disorders may co-occur with impairments in other body systems. In some cases, the impairment in another body system results from a digestive disorder or a skin disorder. In other cases, the impairment in another body system is not related to the digestive disorder or the skin disorder. We intend the listings for digestive disorders to address digestive disorders and the complications of those disorders. We intend the listings for skin disorders to address skin disorders and the complications of those disorders. When the co-occurring condition or complication is due to a digestive disorder or skin disorder, we evaluate it under the digestive disorders listings or skin disorders listings, as appropriate. However, when the co-occurring impairments are unrelated, we evaluate the combination under our medical equivalence rules (as well as our functional equivalence rules for child claimants) at step 3 of the sequential evaluation, or at steps 4 and 5 of the sequential evaluation process for adult claimants. We evaluate unrelated co-occurring impairments at these steps because adjudicators can account for specific combinations of impairments, complications of those impairments, and limitations of functioning on an individual case basis. We address this in the introductory text of the digestive disorders listings at 5.00J and 105.00L (*How do we evaluate digestive disorders that do not meet one of these listings?*) and in the introductory text of the skin disorders listings at 8.00I and 108.00I (*How do we evaluate skin disorders that do not meet one of these listings?*).

What is our authority to make rules and set procedures for determining whether a person is disabled under our statutory definition?

Under the Act, we have authority to make rules and regulations and to establish necessary and appropriate procedures to carry out such provisions.[132]

How long will this final rule be in effect?

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[132] See sections 205(a), 702(a)(5), and 1631(d)(1) (42 U.S.C. 405(a), 902(a)(5), 1383(d)(1)).

This final rule will remain in effect for 5 years after the date it becomes effective, unless we extend, revise, or issue it again. We will continue to monitor this rule to ensure that it continues to meet program purposes and may revise it before the end of the 5-year period if warranted.

How we will implement this final rule?

We will begin to apply this final rule to new applications, pending claims, and continuing disability reviews (CDR), as appropriate, as of the effective date of this final rule.[133]

Regulatory Procedures

Executive Order 12866, as Supplemented by Executive Order 13563

We consulted with the Office of Management and Budget (OMB) and determined that this final rule meets the criteria for a significant regulatory action under Executive Order (E.O.) 12866, as supplemented by E.O. 13563 and is subject to OMB review. Therefore, OMB reviewed the rule. Details about the economic impacts of this rule follow.

Anticipated Costs to Our Programs

In 2018, we conducted a case study covering about 500 initial Disability Determination Service (DDS)-level decisions within the digestive and skin body systems, based on the proposed rule as developed at that time. The case study sample was stratified by specific diagnosis categories and included both listing-level allowances as well as denials at the medical-vocational stage of the disability determination process. Implementation of this final rule would result in decisional changes relative to decisions in these body systems both from allowance to denial and from denial to allowance.

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[133] We will use the final rule beginning on its effective date. We will apply the final rule to new applications filed on or after the effective date, and to claims that are pending on and after the effective date. This means that we will use the final rule on and after its effective date in any case in which we make a determination or decision, including CDRs, as appropriate. See 20 CFR 404.902 and 416.1402.

Estimates presented below reflect some changes to the final rule from the NPRM. The NPRM was used to develop and conduct the original case study. We conducted several different analyses of the original case study to determine the potential effects of the changes in this final rule on the original case study results. Only one of the changes in this final rule affected the case study results, which was the reversion of changes proposed in the NPRM in the digestive listing for weight loss due to any disorder to the criteria used under current rules. Therefore, we expect no decisional changes under this particular weight loss listing in the final rule relative to current policy. Of the other cases found to be affected by the changes in the proposed rule, we concluded that none of them in the case study would have a different decision under the final rule compared to the evaluation under the proposal as they stood at the time of the original case study.

Therefore, based on the results from the case study, we estimate that the combined additional allowances and additional denials under these listings together will likely result in a small net decrease in total allowances for the Old-Age, Survivors and Disability Insurance (OASDI) and SSI programs combined, but different effects for each program separately. For the OASDI program, we estimate net changes from the digestive and skin listings individually that are opposite in effect, a net annual average increase in allowances under the digestive listings of about 100 allowances, and a net annual average decrease under the skin listings of about 95 allowances, with the combined net effect being an increase of about five allowances on an annual average basis. This small net increase results in an estimated net increase of $15 million in scheduled OASDI benefit payments for the listings combined over the projection period fiscal years (FY) 2024-33. For the SSI program, we estimate net reductions for each of the digestive and skin listings individually, with a net annual average decrease in allowances under the digestive listings of about five allowances, and a net annual average decrease in allowances under the skin

listings of about 155 allowances, with the net combined effect being a net decrease of about 160 allowances per year on average.

These estimated effects are based on a stratified random case study of approximately 425 cases, 175 of which were allowed under the listings in effect prior to publication of this rule, and 250 denials. Approximately two-thirds of these cases involved the changes to the digestive listings, and the remaining involved the skin listings. The results of that case study indicated that for each of these listings there would be decisional changes in both directions: some allowances would be denied under these rules, and some denials would be allowed under these rules. The net effects of these changes for the skin listings indicated that the number of cases allowed would be slightly reduced under these new rules for both the OASDI and SSI programs. For the changes to the digestive listings, however, the case study results indicated differing net effects for OASDI and SSI. This is primarily a result of differences in current allowance rates under OASDI and SSI for the specific digestive listings that would be modified by publication of these new rules. OASDI applicants involving digestive impairment have a much lower current allowance rate than similar SSI applicants. Because the case study results indicate changes in both directions, the net effects depend in part on current allowance rates for the listings specifically modified by the changes to the digestive rules.

Our actuarial analysis based on these estimated net changes in SSI allowances indicates a net reduction in Federal SSI payments of $51 million for the listings combined over the projection period FY 2024-33. Estimates are based on the assumption that the new rule would apply to all disability determinations completed beginning October 1, 2023.

Anticipated Administrative Costs to the Social Security Administration

In calculating whether the implementation of this final rule will result in administrative costs or savings to the agency, we examined two sources: (1) Work-years and (2) direct financial administrative costs.

We define work-years as a measure of the SSA employee work time this final rule will cost or save during implementation of its policies. We calculate one work-year as 2,080 hours of labor, which represents the amount of hours one SSA employee works per year based on a standard 40-hour workweek.

The Office of Budget, Finance, and Management estimates net administrative costs of less than 15 work-years and $2 million annually, which we consider to be a non-significant amount.

Anticipated Costs to the Public

We do not believe there are any more than de minimis costs to the public associated with this rulemaking. As discussed earlier in our responses to comments on the Notice of Proposed Rulemaking as well as in the Paperwork Reduction Action section below, the requirements contained in this rulemaking will not impose new additional costs outside of the normal course of business for applicants or change how the public interacts with our disability programs. Most of the revisions made to the digestive and skin listings improve clarity, readability, and application of the listings as well as consistency among the listings as a whole. We do not believe the requirements contained in the new digestive and skin disorders listings will impose additional costs or documentation requirements to applicants or cause the affected applicants to pursue a different course of treatment than they otherwise would have done under our existing rules.

Congressional Review Act

This final rule is not a major rule as defined by the Congressional Review Act.[134]

Executive Order 13132 (Federalism)

We analyzed this final rule in accordance with the principles and criteria established by E.O. 13132, and determined that it will not have sufficient Federalism implications to warrant the preparation of a Federalism assessment. We also determined that the final rule will not preempt any State law or State regulations or affect the States' abilities to discharge traditional State governmental functions.

Regulatory Flexibility Act

We certify that this final rule will not have a significant economic impact on a substantial number of small entities because it affects individuals only. Therefore, the Regulatory Flexibility Act, as amended, does not require us to prepare a regulatory flexibility analysis.

Paperwork Reduction Act

This final rule only updates the criteria in the Listing of Impairments (listings) that we use to evaluate disability claims involving both digestive and skin disorders under titles II and XVI of the Social Security Act but does not create any new or affect any existing collections. Accordingly, it does not impose any burdens under the Paperwork Reduction Act and does not require further OMB approval.

(Catalog of Federal Domestic Assistance Program Nos. 96.001, Social Security–Disability Insurance; 96.002, Social Security–Retirement Insurance; 96.004, Social Security–Survivors Insurance; and 96.006, Supplemental Security Income)

List of Subjects

20 CFR Part 404

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[134] 5 U.S.C. 801 et seq.

Administrative practice and procedure; Blind, Disability benefits; Old-age, survivors, and disability insurance; Reporting and recordkeeping requirements; Social Security.

20 CFR Part 416

Administrative practice and procedure; Aged, Blind, Disability cash payments; Public assistance programs; Reporting and recordkeeping requirements; Supplemental Security Income (SSI).

The Acting Commissioner of Social Security, Kilolo Kijakazi, Ph.D., M.S.W., having reviewed and approved this document, is delegating the authority to electronically sign this document to Faye I. Lipsky, who is the primary Federal Register Liaison for the Social Security Administration, for purposes of publication in the Federal Register.

Faye I. Lipsky,
Federal Register Liaison,
Office of Legislation and Congressional Affairs,
Social Security Administration.

For the reasons set out in the preamble, we are amending subpart P of part 404 of chapter III of title 20 of the Code of Federal Regulations as set forth below:

PART 404—FEDERAL OLD-AGE, SURVIVORS AND DISABILITY INSURANCE (1950-)

Subpart P—Determining Disability and Blindness

1. The authority citation for subpart P of part 404 continues to read as follows:

Authority: Secs. 202, 205(a)-(b) and (d)-(h), 216(i), 221(a) and (h)-(j), 222(c), 223, 225, and 702(a)(5) of the Social Security Act (42 U.S.C. 402, 405(a)-(b) and (d)-(h), 416(i), 421(a) and (h)-(j), 422(c), 423, 425, and 902(a)(5)); sec. 211(b), Pub. L. 104-193, 110 Stat. 2105, 2189; sec. 202, Pub. L. 108-203, 118 Stat. 509 (42 U.S.C. 902 note).

2. Amend appendix 1 to subpart P of part 404 as follows:

a. In the introductory text before part A, revise paragraphs 6 and 9;

b. In part A:

i. Amend the table of contents for part A by revising the entry for section 5.00;

ii. Revise section 5.00;

iii. Amend section 6.00 by revising paragraph 6.00C7;

iv. Revise section 8.00;

v. Amend section 14.00 by revising paragraph 14.00F5;

c. In part B:

i. Amend the table of contents for part B by revising the entry for section 105.00;

ii. Amend section 100.00 by revising paragraph 100.00C2c;

iii. Amend section 103.00 by revising paragraph 103.00K2c;

iv. Amend section 104.00 by revising paragraph 104.00C3b(iii);

v. Revise section 105.00;

vi. Amend section 106.00 by revising paragraph 106.00C5b(iii);

vi. Revise section 108.00; and

viii. Amend section 114.00 by revising paragraph 114.00F7b(iii).

The revisions read as follows:

Appendix 1 to Subpart P of Part 404--Listing of Impairments

* * * * *

6. Digestive Disorders (5.00 and 105.00): [INSERT DATE 120 DAYS AND 5 YEARS FROM THE DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

* * * * *

9. Skin Disorders (8.00 and 108.00): [INSERT DATE 120 DAYS AND 5 YEARS FROM THE DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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Part A

* * * * *

Sec.

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5.00 Digestive Disorders

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5.00 Digestive Disorders

A. *Which digestive disorders do we evaluate in this body system?* We evaluate digestive disorders that result in severe dysfunction of the liver, pancreas, and gastrointestinal tract (the large, muscular tube that extends from the mouth to the anus, where the movement of muscles, along with the release of hormones and enzymes, allows for the digestion of food) in this body system. Examples of these disorders and the listings we use to evaluate them include chronic liver disease (5.05), inflammatory bowel disease (5.06), and intestinal failure (5.07). We also use this body system to evaluate gastrointestinal hemorrhaging from any cause (5.02), weight loss due to any digestive disorder (5.08), liver transplantation (5.09), small intestine transplantation (5.11), and pancreas transplantation (5.12). We evaluate cancers affecting the digestive system under the listings in 13.00.

B. *What evidence do we need to evaluate your digestive disorder?*

1. *General.* To establish that you have a digestive disorder, we need medical evidence about the existence of your digestive disorder and its severity. Medical evidence should include your medical history, physical examination findings, operative reports, and relevant laboratory findings.

2. *Laboratory findings.* We need laboratory reports such as results of imaging (see 5.00B3), endoscopy, and other diagnostic procedures. We may also need clinical

laboratory and pathology results.

3. *Imaging* refers to medical imaging techniques, such as x-ray, ultrasound, magnetic resonance imaging, and computerized tomography. The imaging must be consistent with the prevailing state of medical knowledge and clinical practice as a proper technique to support the evaluation of the disorder.

C. *What is chronic liver disease (CLD), and how do we evaluate it under 5.05?*

1. *General.* CLD is loss of liver function with cell necrosis (cell death), inflammation, or scarring of the liver that persists for more than 6 months. Common causes of CLD in adults include chronic infection with hepatitis B virus or hepatitis C virus, and prolonged alcohol abuse.

a. We will evaluate your signs of CLD, such as jaundice, changes in size of the liver and spleen, ascites, peripheral edema, and altered mental status. We will also evaluate your symptoms of CLD, such as pruritus (itching), fatigue, nausea, loss of appetite, and sleep disturbances when we assess the severity of your impairment(s) and how it affects your ability to function. In the absence of evidence of a chronic liver impairment, episodes of acute liver disease do not meet the requirements of 5.05.

b. *Laboratory findings* of your CLD may include decreased serum albumin, increased International Normalized Ratio (INR), arterial deoxygenation (hypoxemia), increased serum creatinine, oliguria (reduced urine output), or sodium retention. Another laboratory finding that may be included in the evidence is a liver biopsy. If you have had a liver biopsy, we will make every reasonable effort to obtain the results; however, we will not purchase a liver biopsy.

2. *Manifestations of CLD.*

a. *Gastrointestinal hemorrhaging* (5.05A), as a consequence of cirrhosis and high pressure in the liver's portal venous system, may occur from varices (dilated veins in the esophagus or the stomach) or from portal hypertensive gastropathy (abnormal mucosal

changes in the stomach). When gastrointestinal hemorrhaging is due to a cause other than CLD, we evaluate it under 5.02. The phrase "consider under a disability for 1 year" in 5.02 and 5.05A does not refer to the date on which your disability began, only to the date on which we must reevaluate whether your impairment(s) continues to meet a listing or is otherwise disabling. We determine the onset of your disability based on the facts of your case.

b. *Ascites or hydrothorax* (5.05B) is a pathologic accumulation of fluid in the peritoneal cavity (ascites) or pleural space (hydrothorax). Ascites or hydrothorax may be diagnosed by removing some of the fluid with needle aspiration (paracentesis or thoracentesis), physical examination, or imaging. The most common causes of ascites are portal hypertension and low serum albumin resulting from CLD. We evaluate other causes of ascites and hydrothorax that are unrelated to CLD, such as congestive heart failure and cancer, under the listings in the affected body systems.

c. *Spontaneous bacterial peritonitis (SBP)* (5.05C) is an acute bacterial infection of peritoneal fluid and is most commonly associated with CLD. SBP is diagnosed by laboratory analysis of peritoneal fluid (obtained by paracentesis) that contains a neutrophil count (also called absolute neutrophil count) of at least 250 cells/mm^3. 5.05C is satisfied with one evaluation documenting peritoneal infection. We evaluate other causes of peritonitis that are unrelated to CLD, such as tuberculosis, malignancy, and perforated bowel, under the listings in the affected body systems.

d. *Hepatorenal syndrome* (5.05D) is renal failure associated with CLD in the absence of underlying kidney pathology. Findings associated with hepatorenal syndrome include elevation of serum creatinine, sodium retention with low urinary sodium excretion, and oliguria. We evaluate renal dysfunction with known underlying kidney pathology, such as glomerulonephritis, tubular necrosis, and renal infections, under the listings in 6.00.

e. *Hepatopulmonary syndrome* (5.05E) is arterial deoxygenation due to intrapulmonary vascular dilation and arteriovenous shunting associated with CLD. Clinical findings of hepatopulmonary syndrome include platypnea (shortness of breath relieved when lying down) and orthodeoxia (low arterial blood oxygen while in the upright position), when presenting in the context of CLD. We evaluate pulmonary dysfunction with known underlying respiratory pathology, such as asthma, pneumonia, and pulmonary infections, under the listings in 3.00.

(i) Under 5.05E1, we require a resting arterial blood gas (ABG) measurement obtained while you are breathing room air; that is, without oxygen supplementation. The ABG report must include the P_aO_2 value, your name, the date of the test, and either the altitude or both the city and State of the test site.

(ii) We will not purchase the specialized imaging techniques described in 5.05E2; however, if you have had the test(s) at a time relevant to your claim, we will make every reasonable effort to obtain the report.

f. *Hepatic encephalopathy* (5.05F), also known as portosystemic encephalopathy, is a recurrent or chronic neuropsychiatric disorder associated with CLD.

(i) Under 5.05F2, we require documentation of a mental impairment associated with hepatic encephalopathy. A mental impairment can include abnormal behavior, changes in mental status, or an altered state of consciousness. Reports of abnormal behavior may show that you are experiencing delusions, paranoia, or hallucinations. Reports of changes in mental status may show change in sleep patterns, personality or mood changes, poor concentration, or poor judgment or cognitive dysfunction (for example, impaired memory, poor problem-solving ability, or attention deficits). Reports of altered state of consciousness may show that you are experiencing confusion, delirium, or stupor.

(ii) Signs and laboratory findings that document the severity of hepatic

encephalopathy when not attributable to other causes may include a “flapping tremor” (asterixis), characteristic abnormalities found on an electroencephalogram (EEG), or abnormal serum albumin or coagulation values. We will not purchase an EEG; however, if you have had this test at a time relevant to your claim, we will make every reasonable effort to obtain the report for the purpose of establishing whether your impairment meets the criteria of 5.05F.

(iii) We will not evaluate acute encephalopathy under 5.05F if it results from conditions other than CLD. For example, we will evaluate acute encephalopathy caused by vascular events under the listings in 11.00 and acute encephalopathy caused by cancer under the listings in 13.00.

3. *SSA Chronic Liver Disease (SSA CLD) score* (5.05G). Listing 5.05G requires two SSA CLD scores, each requiring three or four laboratory values. The “date of the SSA CLD score” is the date of the earliest of the three or four laboratory values used for its calculation. The date of the second SSA CLD score must be at least 60 days after the date of the first SSA CLD score and both scores must be within the required 12-month period. If you have the two SSA CLD scores required by 5.05G, we will find that your impairment meets the criteria of the listing from at least the date of the first SSA CLD score.

a. We calculate the SSA CLD score using a formula that includes up to four laboratory values: Serum creatinine (mg/dL), total bilirubin (mg/dL), INR, and under certain conditions, serum sodium (mmol/L). The SSA CLD score calculation contains at least one, and sometimes two, parts, as described in (i) and (ii).

(i) The initial calculation is:

$$\begin{aligned}&\text{SSA CLD}_i = \\ &9.57 \times [\log_e(\text{serum creatinine mg/dL})] \\ &+ 3.78 \times [\log_e(\text{serum total bilirubin mg/dL})] \\ &+11.2 \times [\log_e(\text{INR})] \\ &+ 6.43\end{aligned}$$

rounded to the nearest whole integer.

(ii) If the value from the initial calculation is 11 or below, the SSA CLD score will be the SSA CLD_i value. If the value from the initial calculation is greater than 11, the SSA CLD score will be re-calculated as:

SSA CLD =
SSA CLD_i
+ 1.32 × (137 - serum sodium mmol/L)
- [0.033 × SSA CLD_i × (137 - serum sodium mmol/L)]

(iii) We round the results of your SSA CLD score calculation to the nearest whole integer to arrive at your SSA CLD score.

b. For any SSA CLD score calculation, all of the required laboratory values (serum creatinine, serum total bilirubin, INR, and serum sodium) must have been obtained within a continuous 30-day period.

(i) We round values for serum creatinine (mg/dL), serum total bilirubin (mg/dL), or INR less than 1.0 up to 1.0 to calculate your SSA CLD score.

(ii) We round values for serum creatinine (mg/dL) greater than 4.0 down to 4.0 to calculate your SSA CLD score.

(iii) If there are multiple laboratory values within the 30-day interval for serum creatinine (mg/dL), serum total bilirubin (mg/dL), or INR, we use the *highest* value to calculate your SSA CLD score. We will not use any INR values derived from testing done while you are on anticoagulant treatment in our SSA CLD calculation.

(iv) If there are multiple laboratory values within the 30-day interval for serum sodium (mmol/L), we use the *lowest* value to calculate your SSA CLD score.

(v) If you are in renal failure or on renal dialysis within a week of any serum creatinine test in the period used for the SSA CLD calculation, we will use a serum creatinine value of 4.0, which is the maximum serum creatinine level allowed in the calculation, to calculate your SSA CLD score.

(vi) If your serum sodium is less than 125 mmol/L, we will set your serum sodium to 125 mmol/L for purposes of calculation of the SSA CLD score. If your serum sodium is higher than 137 mmol/L, we will set your serum sodium to 137 mmol/L for purposes of calculation of the SSA CLD score.

c. When we indicate "$\log_e$" (also abbreviated "ln") in the formula for the SSA CLD score calculation, we mean the "base e logarithm" or "natural logarithm" of the numerical laboratory value, not the "base 10 logarithm" or "common logarithm" (log) of the laboratory value, and not the actual laboratory value. For example, if a person has laboratory values of serum creatinine 1.4 mg/dL, serum total bilirubin 1.3 mg/dL, INR 1.32, and serum sodium 119 mmol/L, we compute the SSA CLD score as follows:

$$
\begin{aligned}
&\text{SSA CLD}_i = \\
&9.57 \times [\log_e(\text{serum creatinine 1.4 mg/dL}) = 0.336] \\
&+ 3.78 \times [\log_e(\text{serum total bilirubin 1.3 mg/dL}) = 0.262] \\
&+ 11.2 \times [\log_e(\text{INR 1.32}) = .278] \\
&+ 6.43 \\
&= 3.22 + 0.99 + 3.11 + 6.43 \\
&= 13.75, \text{ which we round to an SSA CLD}_i \text{ score of 14.}
\end{aligned}
$$

Because the SSA CLDi score is over 11, we then move to the second step of calculating the SSA CLD:

$$
\begin{aligned}
&\text{SSA CLD} = \\
&14 \\
&+ 1.32 \times (137 - \text{serum sodium 125 mmol/L}) \\
&- [0.033 \times \text{SSA CLD}_i\ 14 \times (137 - \text{serum sodium 125 mmol/L}) \\
&= 14 + 15.84 - 5.54 \\
&= 24.3, \text{ which we round to an SSA CLD score of 24.}
\end{aligned}
$$

D. *What is inflammatory bowel disease (IBD), and how do we evaluate it under 5.06?*

1. IBD is a group of inflammatory conditions of the small intestine and colon. The most common IBD disorders are Crohn's disease and ulcerative colitis. Remissions and exacerbations of variable duration are a hallmark of IBD.

2. We evaluate your signs and symptoms of IBD, such as diarrhea, fecal

incontinence, rectal bleeding, abdominal pain, fatigue, fever, nausea, vomiting, arthralgia, abdominal tenderness, palpable abdominal mass (usually inflamed loops of bowel), and perianal disease (for example, fissure, fistulas, abscesses, or anal canal stenosis), when we assess the severity of your impairment(s). You may require supplemental daily nutrition due to IBD. There are two forms of supplemental daily nutrition we consider under 5.06B5: enteral nutrition (delivered directly to a part of your digestive system) via a gastrostomy, duodenostomy, or jejunostomy, and parenteral nutrition delivered via a central venous catheter. Enteral tube feedings delivered via nasal or oral tubes do not satisfy the requirement in 5.06B5.

3. Surgical diversion of the intestinal tract, including ileostomy and colostomy, does not preclude the ability to perform any gainful activity if you are able to maintain adequate nutrition and function of the stoma. However, if you are not able to maintain adequate nutrition, we will evaluate your impairment under 5.08.

4. IBD may also be associated with significant extraintestinal manifestations in a variety of body systems. These include, but are not limited to, involvement of the eye (for example, uveitis, episcleritis, or iritis); hepatobiliary disease (for example, gallstones or primary sclerosing cholangitis); urologic disease (for example, kidney stones or obstructive hydronephrosis); skin involvement (for example, erythema nodosum or pyoderma gangrenosum); or non-destructive inflammatory arthritis. You may also have associated thromboembolic disorders or vascular disease. These manifestations may not correlate with the severity of your IBD. If your impairment does not meet any of the criteria of 5.06, we will consider the effects of your extraintestinal manifestations in determining whether you have an impairment(s) that meets or medically equals another listing, and when we assess your residual functional capacity.

5. *Repeated complications of IBD.*

a. Examples of complications of IBD include abscesses, intestinal perforation,

toxic megacolon, infectious colitis, pyoderma gangrenosum, ureteral obstruction, primary sclerosing cholangitis, and hypercoagulable state (which may lead to thromboses or embolism). When we evaluate repeated complications of IBD, we consider all relevant information in your case record to determine the effects of your IBD on your ability to function independently, appropriately, effectively, and on a sustained basis. Factors we consider include, but are not limited to: your symptoms, the frequency and duration of your complications, periods of exacerbation and remission, and the functional effects of your treatment, including the side effects of your medication. Your impairment will satisfy this criterion regardless of whether you have the same kind of complication repeatedly, all different complications, or any other combination of complications; for example, two of the same kind of complication and a different one.

b. To satisfy the requirements described under 5.06C, your IBD must result in repeated complications and marked limitation in one of three areas of functioning: activities of daily living; maintaining social functioning; or completing tasks in a timely manner due to deficiencies in concentration, persistence, or pace. If the complications do not last as long or occur as frequently as required under 5.06C, we will consider whether your IBD medically equals the listing.

c. *Marked* limitation means that the signs and symptoms of your IBD interfere *seriously* with your ability to function. Although we do not require the use of such a scale, “marked” would be the fourth point on a five-point rating scale consisting of no limitation, mild limitation, moderate limitation, marked limitation, and extreme limitation. We do not define “marked” by a specific number of activities of daily living or different behaviors in which your social functioning is impaired, or a specific number of tasks that you are able to complete, but by the nature and overall degree of interference with your functioning. You may have marked limitation when several activities or functions are impaired, or when only one is impaired. Additionally, you need not be

totally precluded from performing an activity to have marked limitation, as long as the degree of limitation interferes seriously with your ability to function independently, appropriately, and effectively. The term "marked" does not imply that you must be confined to bed, hospitalized, or in a nursing home.

d. *Activities of daily living* include, but are not limited to, such activities as doing household chores, grooming and hygiene, using a post office, taking public transportation, or paying bills. We will find that you have "marked" limitation in activities of daily living if you have a serious limitation in your ability to maintain a household or take public transportation because of symptoms, such as pain, severe fatigue, anxiety, or difficulty concentrating, caused by your IBD (including complications of the disorder) or its treatment, even if you are able to perform some self-care activities.

e. *Maintaining social functioning* includes the capacity to interact independently, appropriately, effectively, and on a sustained basis with others. It includes the ability to communicate effectively with others. We will find that you have "marked" limitation in maintaining social functioning if you have a serious limitation in social interaction on a sustained basis because of symptoms, such as pain, severe fatigue, anxiety, or difficulty concentrating, or a pattern of exacerbation and remission, caused by your IBD (including complications of the disorder) or its treatment, even if you are able to communicate with close friends or relatives.

f. *Completing tasks in a timely manner due to deficiencies in concentration, persistence, or pace* involves the ability to sustain concentration, persistence, or pace to permit timely completion of tasks commonly found in work settings. We will find that you have "marked" limitation in completing tasks if you have a serious limitation in your ability to sustain concentration or pace adequate to complete work-related tasks because of symptoms, such as pain, severe fatigue, anxiety, or difficulty concentrating, caused by your IBD (including complications of the disorder) or its treatment, even if you are able

to do some routine activities of daily living.

E. *What is intestinal failure, and how do we evaluate it under 5.07?*

1. *Intestinal failure* is a condition resulting in gut function below the minimum necessary for the absorption of macronutrients or water and electrolytes, resulting in a requirement for intravenous supplementation (i.e., parenteral nutrition) to maintain health. Examples of conditions that may result in intestinal failure include short bowel syndrome, extensive small bowel mucosal disease, and chronic motility disorders.

2. *Short bowel syndrome* is a malabsorption disorder that occurs when ischemic vascular insults (caused, for example, by volvulus or necrotizing enterocolitis), trauma, or IBD complications require(s) surgical resection of any amount of the small intestine, resulting in chronic malnutrition.

3. *Extensive small bowel mucosal disease* means that the mucosal surface of the small bowel does not efficiently absorb nutrients or loses nutrients. Common causes of small bowel mucosal disease include microvillous inclusion disease and tufting enteropathy.

4. *Chronic motility disorder* refers to a chronic disorder of the propulsion of gut content without fixed obstructions, causing intolerance to oral nutrition and inadequate nutritional intake. This type of disorder may also be known as a chronic intestinal pseudo-obstruction (CIPO), because the gut dysfunction mimics that of an obstructed intestine, but without evidence of an actual obstruction. Primary CIPO may have an unknown underlying cause. Chronic motility disorders may also result from congenital, neuromuscular, or autoimmune conditions, such as gastroschisis, omphalocele, long segment Hirschprung's disease, Crohn's disease, and mitochondrial disorders.

5. For short bowel syndrome, we require a copy of the operative report that includes details of the surgical findings, or postoperative imaging indicating a resection of the small intestine. If we cannot get one of these reports, we need other medical reports

that include details of the surgical findings. For other chronic motility disorders or extensive small bowel mucosal disease, we need medical reports that include details of your intestinal dysfunction. For any impairment evaluated under 5.07, we also need medical documentation that you are dependent on daily parenteral nutrition to provide most of your nutritional requirements.

F. *How do we evaluate weight loss due to any digestive disorder under 5.08?*

1. In addition to the impairments specifically mentioned in these listings, other digestive disorders, such as esophageal stricture, pancreatic insufficiency, and malabsorption, may result in significant weight loss. Impairments other than digestive disorders that cause weight loss should be evaluated under the appropriate body system for that impairment. For instance, weight loss as a result of chronic kidney disease should be evaluated under our rules for genitourinary disorders (see 6.00), and weight loss as the result of an eating disorder should be evaluated under our rules for mental disorders (see 12.00). However, if you develop a digestive disorder as the result of your other impairment, we will evaluate the acquired digestive disorder under our rules for digestive disorders. We evaluate weight loss due to any digestive disorder under 5.08 by using the body mass index (BMI).

2. BMI is the ratio of your weight to the square of your height. Calculation and interpretation of the BMI are independent of gender in adults.

a. We calculate BMI using inches and pounds, meters and kilograms, or centimeters and kilograms. We must have measurements of your weight and height without shoes for these calculations.

b. We calculate BMI using one of the following formulas:

English Formula

BMI = [Weight in Pounds / (Height in Inches × Height in Inches)] × 703

Metric Formulas

BMI = Weight in Kilograms / (Height in Meters × Height in Meters)

BMI = [Weight in Kilograms / (Height in Centimeters × Height in Centimeters)] × 10,000

G. *How do we evaluate digestive organ transplantation?* If you receive a liver (5.09), small intestine (5.11), or pancreas (5.12) transplant, we will consider you disabled under the listing for 1 year from the date of the transplant. After that, we evaluate your residual impairment(s) by considering the adequacy of your post-transplant function, the frequency and severity of any rejection episodes you have, complications in other body systems, and adverse treatment effects. People who receive digestive organ transplants generally have impairments that meet our definition of disability before they undergo transplantation. The phrase "consider under a disability for 1 year" in 5.09, 5.11, and 5.12 does not refer to the date on which your disability began, only to the date on which we must reevaluate whether your impairment(s) continues to meet a listing or is otherwise disabling. We determine the onset of your disability based on the facts of your case.

H. *How do we evaluate your digestive disorder if there is no record of ongoing treatment?* If there is no record of ongoing treatment despite the existence of a severe impairment(s), we will assess the severity and duration of your digestive disorder based on the current medical and other evidence in your case record. If there is no record of ongoing treatment, you may not be able to show an impairment that meets a digestive disorders listing, but your impairment may medically equal a listing, or be disabling based on consideration of your residual functional capacity, age, education, and work experience.

I. *How do we evaluate your digestive disorder if there is evidence establishing a substance use disorder?* If we find that you are disabled and there is medical evidence in your case record establishing that you have a substance use disorder, we will determine whether your substance use disorder is a contributing factor material to the determination

of disability. See §§ 404.1535 and 416.935 of this chapter. Digestive disorders resulting from drug or alcohol use are often chronic in nature and will not necessarily improve with cessation in drug or alcohol use.

J. *How do we evaluate digestive disorders that do not meet one of these listings?*

1. These listings are only examples of common digestive disorders that we consider severe enough to prevent you from doing any gainful activity. If your impairment(s) does not meet the criteria of any of these listings, we must also consider whether you have an impairment(s) that satisfies the criteria of a listing in another body system.

2. If you have a severe medically determinable impairment(s) that does not meet a listing, we will determine whether your impairment(s) medically equals a listing. See §§ 404.1526 and 416.926 of this chapter. Digestive disorders may be associated with disorders in other body systems, and we consider the combined effects of multiple impairments when we determine whether they medically equal a listing. If your impairment(s) does not meet or medically equal a listing, you may or may not have the residual functional capacity to engage in substantial gainful activity. We proceed to the fourth step and, if necessary, the fifth step of the sequential evaluation process in §§ 404.1520 and 416.920 of this chapter. We use the rules in §§ 404.1594 and 416.994 of this chapter, as appropriate, when we decide whether you continue to be disabled.

5.01 Category of Impairments, Digestive Disorders

5.02 *Gastrointestinal hemorrhaging from any cause, requiring three blood transfusions* of at least 2 units of blood per transfusion, within a consecutive 12-month period and at least 30 days apart. Consider under a disability for 1 year following the last documented transfusion; after that, evaluate the residual impairment(s).

5.03–5.04 [Reserved]

5.05 *Chronic liver disease (CLD)* (see 5.00C) with A, B, C, D, E, F, or G:

A. Hemorrhaging from esophageal, gastric, or ectopic varices, or from portal hypertensive gastropathy (see 5.00C2a), documented by imaging (see 5.00B3); resulting in 1 and 2:

1. Hemodynamic instability indicated by signs such as pallor (pale skin), diaphoresis (profuse perspiration), rapid pulse, low blood pressure, postural hypotension (pronounced fall in blood pressure when arising to an upright position from lying down), or syncope (fainting); and

2. Requiring hospitalization for transfusion of at least 2 units of blood. Consider under a disability for 1 year following the documented transfusion; after that, evaluate the residual impairment(s).

OR

B. Ascites or hydrothorax not attributable to other causes (see 5.00C2b), present on two evaluations within a consecutive 12-month period and at least 60 days apart. Each evaluation must document the ascites or hydrothorax by 1, 2, or 3:

1. Paracentesis; or

2. Thoracentesis; or

3. Imaging or physical examination with a or b:

a. Serum albumin of 3.0 g/dL or less; or

b. INR of at least 1.5.

OR

C. Spontaneous bacterial peritonitis (see 5.00C2c) documented by peritoneal fluid containing a neutrophil count of at least 250 cells/mm^3.

OR

D. Hepatorenal syndrome (see 5.00C2d) documented by 1, 2, or 3:

1. Serum creatinine elevation of at least 2 mg/dL; or

2. Oliguria with 24-hour urine output less than 500 mL; or

3. Sodium retention with urine sodium less than 10 mEq per liter.

OR

E. Hepatopulmonary syndrome (see 5.00C2e) documented by 1 or 2:

1. Arterial P_aO_2 measured by an ABG test, while at rest, breathing room air, less than or equal to:

a. 60 mm Hg, at test sites less than 3,000 feet above sea level; or

b. 55 mm Hg, at test sites from 3,000 through 6,000 feet above sea level; or

c. 50 mm Hg, at test sites over 6,000 feet above sea level; or

2. Intrapulmonary arteriovenous shunting as shown by contrast-enhanced echocardiography or macroaggregated albumin lung perfusion scan.

OR

F. Hepatic encephalopathy (see 5.00C2f) with documentation of abnormal behavior, cognitive dysfunction, changes in mental status, or altered state of consciousness (for example, confusion, delirium, stupor, or coma), present on two evaluations within a consecutive 12-month period and at least 60 days apart and either 1 or 2:

1. History of transjugular intrahepatic portosystemic shunt (TIPS) or other surgical portosystemic shunt; or

2. One of the following on at least two evaluations at least 60 days apart within the same consecutive 12-month period as in F:

a. Asterixis or other fluctuating physical neurological abnormalities; or

b. EEG demonstrating triphasic slow wave activity; or

c. Serum albumin of 3.0 g/dL or less; or

d. INR of 1.5 or greater.

OR

G. Two SSA CLD scores (see 5.00C3) of at least 20 within a consecutive 12-

month period and at least 60 days apart. Consider under a disability from at least the date of the first score.

5.06 *Inflammatory bowel disease (IBD)* (see 5.00D) documented by endoscopy, biopsy, imaging, or operative findings, *and* demonstrated by A, B, or C:

A. Obstruction of stenotic areas (not adhesions) in the small intestine or colon with proximal dilatation, confirmed by imaging or in surgery, requiring two hospitalizations for intestinal decompression or for surgery, within a consecutive 12-month period and at least 60 days apart.

OR

B. Two of the following occurring within a consecutive 12-month period and at least 60 days apart:

1. Anemia with hemoglobin of less than 10.0 g/dL, present on at least two evaluations at least 60 days apart; or

2. Serum albumin of 3.0 g/dL or less, present on at least two evaluations at least 60 days apart; or

3. Clinically documented tender abdominal mass palpable on physical examination with abdominal pain or cramping; or

4. Perianal disease with a draining abscess or fistula; or

5. Need for supplemental daily enteral nutrition via a gastrostomy, duodenostomy, or jejunostomy, or daily parenteral nutrition via a central venous catheter.

OR

C. Repeated complications of IBD (see 5.00D5a), occurring an average of 3 times a year, or once every 4 months, each lasting 2 weeks or more, within a consecutive 12-month period, and marked limitation (see 5.00D5c) in one of the following:

1. Activities of daily living (see 5.00D5d); or

2. Maintaining social functioning (see 5.00D5e); or

3. Completing tasks in a timely manner due to deficiencies in concentration, persistence, or pace (see 5.00D5f).

5.07 *Intestinal failure* (see 5.00E) due to short bowel syndrome, chronic motility disorders, or extensive small bowel mucosal disease, resulting in dependence on daily parenteral nutrition via a central venous catheter for at least 12 months.

5.08 *Weight loss due to any digestive disorder* (see 5.00F), despite adherence to prescribed medical treatment, with BMI of less than 17.50 calculated on at least two evaluations at least 60 days apart within a consecutive 12-month period.

5.09 *Liver transplantation* (see 5.00G). Consider under a disability for 1 year from the date of the transplant; after that, evaluate the residual impairment(s).

5.10 [Reserved]

5.11 *Small intestine transplantation* (see 5.00G). Consider under a disability for 1 year from the date of the transplant; after that, evaluate the residual impairment(s).

5.12 *Pancreas transplantation* (see 5.00G). Consider under a disability for 1 year from the date of the transplant; after that, evaluate the residual impairment(s).

6.00 Genitourinary Disorders

* * * * *

C. * * *

7. *Anorexia (diminished appetite) with weight loss*. Anorexia is a frequent sign of CKD and can result in weight loss. We will use body mass index (BMI) to determine the severity of your weight loss under 6.05B4. (BMI is the ratio of your measured weight to the square of your measured height.) We calculate your BMI using the formulas in the digestive disorders body system (5.00).

* * * * *

8.00 Skin Disorders

A. *Which skin disorders do we evaluate under these listings?* We use these

listings to evaluate skin disorders that result from hereditary, congenital, or acquired pathological processes. We evaluate genetic photosensitivity disorders (8.07), burns (8.08), and chronic conditions of the skin or mucous membranes such as ichthyosis, bullous disease, dermatitis, psoriasis, and hidradenitis suppurativa (8.09) under these listings.

B. *What are our definitions for the following terms used in this body system?*

1. *Assistive device(s):* An assistive device, for the purposes of these listings, is any device used to improve stability, dexterity, or mobility. An assistive device can be hand-held, such as a cane(s), a crutch(es), or a walker; used in a seated position, such as a wheelchair, rollator, or power operated vehicle; or worn, such as a prosthesis or an orthosis.

2. *Chronic skin lesions:* Chronic skin lesions can have recurrent exacerbations (see 8.00B7). They can occur despite prescribed medical treatment. These chronic skin lesions can develop on any part of your body, including upper extremities, lower extremities, palms of your hands, soles of your feet, the perineum, inguinal (groin) region, and axillae (underarms). Chronic skin lesions may result in functional limitations as described in 8.00D2.

3. *Contractures:* Contractures are permanent fibrous scar tissue resulting in tightening and thickening of skin that prevents normal movement of the damaged area. They can develop on any part of your musculoskeletal system, including upper extremities, lower extremities, palms of your hands, soles of your feet, the perineum, inguinal (groin) region, and axillae (underarms). Contractures may result in functional limitations as described in 8.00D2.

4. *Documented medical need:* When we use the term “documented medical need,” we mean that there is evidence (see §§ 404.1513 and 416.913 of this chapter) from your medical source(s) in the medical record that supports your need for an assistive device

(see 8.00B1) for a continuous period of at least 12 months. The evidence must include documentation from your medical source(s) describing any limitation(s) in your upper or lower extremity functioning that supports your need for the assistive device and describing the circumstances for which you need it. The evidence does not have to include a specific prescription for the device.

5. *Fine and gross movements:* Fine movements, for the purposes of these listings, involve use of your wrists, hands, and fingers; such movements include picking, pinching, manipulating, and fingering. Gross movements involve use of your shoulders, upper arms, forearms, and hands; such movements include handling, gripping, grasping, holding, turning, and reaching. Gross movements also include exertional activities such as lifting, carrying, pushing, and pulling.

6. *Surgical management:* For the purposes of these listings, surgical management includes the surgery(ies) itself, as well as various post-surgical procedures, surgical complications, infections or other medical complications, related illnesses, or related treatments that delay a person's attainment of maximum benefit from surgery.

7. *Exacerbation:* For the purposes of these listings, exacerbation means an increase in the signs or symptoms of the skin disorder. Exacerbation may also be referred to as flare, flare-up, or worsening of the skin disorder.

C. *What evidence do we need to evaluate your skin disorder?*

1. To establish the presence of a skin disorder as a medically determinable impairment, we need objective medical evidence from an acceptable medical source (AMS) who has examined you for the disorder.

2. We will make every reasonable effort to obtain your medical history, treatment records, and relevant laboratory findings, but we will not purchase genetic testing.

3. When we evaluate the presence and severity of your skin disorder(s), we generally need information regarding:

a. The onset, duration, and frequency of exacerbations (see 8.00B7);

b. The prognosis of your skin disorder;

c. The location, size, and appearance of lesions and contractures;

d. Any available history of familial incidence;

e. Your exposure to toxins, allergens or irritants; seasonal variations; and stress factors;

f. Your ability to function outside of a highly protective environment (see 8.00E4);

g. Laboratory findings (for example, a biopsy obtained independently of Social Security disability evaluation or results of blood tests);

h. Evidence from other medically acceptable methods consistent with the prevailing state of medical knowledge and clinical practice; and

i. Statements you or others make about your disorder(s), your restrictions, and your daily activities.

D. *How do we evaluate the severity of skin disorders?*

1. *General.* We evaluate the severity of skin disorders based on the site(s) of your chronic skin lesions (see 8.00B2) or contractures (see 8.00B3), functional limitations caused by your signs and symptoms (including pain) (see 8.00D2), and how your prescribed treatment affects you. We consider the frequency and severity of your exacerbations (see 8.00B7), how quickly they resolve, and how you function between exacerbations (see 8.00B7), to determine whether your skin disorder meets or medically equals a listing (see 8.00D3). If there is no record of ongoing medical treatment for your disorder, we will follow the guidelines in 8.00D6. We will determine the extent and kinds of evidence we need from medical and non-medical sources based on the individual facts about your disorder. For our basic rules on evidence, see §§ 404.1512, 404.1513, 404.1520b, 416.912, 416.913, and 416.920b of this chapter. For our rules on evaluating

your symptoms, see §§ 404.1529 and 416.929 of this chapter.

2. *Limitation(s) of physical functioning due to skin disorders.*

a. Skin disorders may be due to chronic skin lesions (see 8.00B2) or contractures (see 8.00B3), and may cause pain or restrict movement, which can limit your ability to initiate, sustain, and complete work-related activities. For example, skin lesions in the axilla may limit your ability to raise or reach with the affected arm, or lesions in the inguinal region may limit your ability to ambulate, sit, or lift and carry. To evaluate your skin disorder(s) under 8.07B, 8.08, and 8.09, we require medically documented evidence of physical limitation(s) of functioning related to your disorder. The decrease in physical function must have lasted, or can be expected to last, for a continuous period of at least 12 months (see §§ 404.1509 and 416.909 of this chapter). Xeroderma pigmentosum is the only skin disorder that does not include functional criteria because the characteristics and severity of the disorder itself are sufficient to meet the criteria in 8.07A.

b. The functional criteria require impairment-related physical limitations in using upper or lower extremities that have lasted, or can be expected to last, for a continuous period of at least 12 months, medically documented by one of the following:

(i) Inability to use both upper extremities to the extent that neither can be used to independently initiate, sustain, and complete work-related activities involving fine and gross movements (see 8.00B5) due to chronic skin lesions (see 8.00B2) or contractures (see 8.00B3); or

(ii) Inability to use one upper extremity to independently initiate, sustain, and complete work-related activities involving fine and gross movements (see 8.00B5) due to chronic skin lesions (see 8.00B2) or contractures (see 8.00B3), and a documented medical need (see 8.00B4) for an assistive device (see 8.00B1) that requires the use of the other upper extremity; or

(iii) Inability to stand up from a seated position and maintain an upright position

to the extent needed to independently initiate, sustain, and complete work-related activities due to chronic skin lesions (see 8.00B2) or contractures (see 8.00B3) affecting at least two extremities (including when the limitations are due to involvement of the perineum or the inguinal region); or

(iv) Inability to maintain an upright position while standing or walking to the extent needed to independently initiate, sustain, and complete work-related activities due to chronic skin lesions (see 8.00B2) or contractures (see 8.00B3) affecting both lower extremities (including when the limitations are due to involvement of the perineum or the inguinal region).

3. *Frequency of exacerbations due to chronic skin lesions.* A skin disorder resulting in chronic skin lesions (see 8.00B2) may have frequent exacerbations (see 8.00B7) severe enough to meet a listing even if each individual skin lesion exacerbation (see 8.00B7) did not last for an extended amount of time. We will consider the frequency, severity, and duration of skin lesion exacerbations (see 8.00B7), how quickly they resolve, and how you function in the time between skin lesion exacerbations (see 8.00B7), to determine whether your skin disorder meets or medically equals a listing.

4. *Symptoms (including pain).* Your symptoms may be an important factor in our determination of whether your skin disorder(s) meets or medically equals a listing, or whether you are otherwise able to work. We consider your symptoms only when you have a medically determinable impairment that could reasonably be expected to produce the symptoms. See §§ 404.1529 and 416.929 of this chapter.

5. *Treatment.*

a. *General.* Treatments for skin disorders may have beneficial or adverse effects, and responses to treatment vary from person to person. Your skin disorder's response to treatment may vary due to treatment resistance or side effects that can result in functional limitations. We will evaluate all of the effects of treatment (including surgical treatment,

medications, and therapy) on the symptoms, signs, and laboratory findings of your skin disorder, and on your ability to function.

b. *Despite adherence to prescribed medical treatment for 3 months.* Under 8.09, we require that your symptoms persist "despite adherence to prescribed medical treatment for 3 months." This requirement means that you must have taken prescribed medication(s) or followed other medical treatment prescribed by a medical source for 3 consecutive months. Treatment or effects of treatment may be temporary. In most cases, sufficient time must elapse to allow us to evaluate your response to treatment, including any side effects. For our purposes, "sufficient time" means a period of at least 3 months. If your treatment has not lasted for at least 3 months, we will follow the rules in 8.00D6a. The 3 months adherence to prescribed medical treatment must be within the period of at least 12 months that we use to evaluate severity.

c. *Treatment with PUVA (psoralen and ultraviolet A (UVA) light) or biologics.* If you receive additional treatment with PUVA or biologics to treat your skin disorder(s), we will defer adjudication of your claim for 6 months from the start of treatment with PUVA or biologics to evaluate the effectiveness of these treatments unless we can make a fully favorable determination or decision on another basis.

6. *No record of ongoing treatment.*

a. Despite having a skin disorder, you may not have received ongoing treatment, may have just begun treatment, may not have access to prescribed medical treatment, or may not have an ongoing relationship with the medical community. In any of these situations, you will not have a longitudinal medical record for us to review when we evaluate your disorder. In some instances, we may be able to assess the severity and duration of your skin disorder based on your medical record and current evidence alone. We may ask you to attend a consultative examination to determine the severity and potential duration of your skin disorder (see §§ 404.1519a and 416.919a of this chapter).

b. If, for any reason, you have not received treatment, your skin disorder cannot meet the criteria for 8.09. If the information in your case record is not sufficient to show that you have a skin disorder that meets the criteria of one of the skin disorders listings, we will follow the rules in 8.00I.

E. *How do we evaluate genetic photosensitivity disorders under 8.07?* Genetic photosensitivity disorders are disorders of the skin caused by an increase in the sensitivity of the skin to sources of ultraviolet light, including sunlight.

1. *Xeroderma pigmentosum (XP) (8.07A).* XP is a genetic photosensitivity disorder with lifelong hypersensitivity to all forms of ultraviolet light. Laboratory testing confirms the diagnosis by documenting abnormalities in the body's ability to repair DNA (deoxyribonucleic acid) mutations after ultraviolet light exposure. Your skin disorder meets the requirements of 8.07A if you have clinical and laboratory findings supporting a diagnosis of XP (see 8.00E3).

2. *Other genetic photosensitivity disorders (8.07B).* The effects of other genetic photosensitivity disorders may vary and may not persist over time. To meet the requirements of 8.07B, a genetic photosensitivity disorder other than XP must be established by clinical and laboratory findings (see 8.00C) and must result either in chronic skin lesions (see 8.00B2) or contractures (see 8.00B3) that result in functional limitations (see 8.00D2), or must result in the inability to function outside of a highly protective environment (see 8.00E4). Some genetic photosensitivity disorders can have very serious effects on other body systems, especially special senses and speech, neurological, mental, and cancer. We will evaluate your disorder(s) under the listings in 2.00, 11.00, 12.00, or 13.00, as appropriate.

3. *What evidence do we need to document that you have XP or another genetic photosensitivity disorder?* We will make a reasonable effort to obtain evidence of your disorder(s), but we will not purchase genetic testing. When the results of genetic tests are

part of the existing evidence in your case record, we will evaluate the test results with all other relevant evidence. We need the following clinical and laboratory findings to document that you have XP or another genetic photosensitivity disorder:

a. A laboratory report of a definitive genetic test documenting appropriate chromosomal changes, including abnormal DNA repair or another DNA abnormality specific to your type of photosensitivity disorder, signed by an AMS; or

b. A laboratory report of a definitive test that is not signed by an AMS, and a report from an AMS stating that you have undergone definitive genetic laboratory studies documenting appropriate chromosomal changes, including abnormal DNA repair or another DNA abnormality specific to your type of photosensitivity disorder; or

c. If we do not have a laboratory report of a definitive test, we need documentation from an AMS that an appropriate laboratory analysis or other diagnostic method(s) confirms a positive diagnosis of your skin disorder. This documentation must state that you had the appropriate definitive laboratory test(s) for diagnosing your disorder and provide the results, or explain how another diagnostic method(s), consistent with the prevailing state of medical knowledge and clinical practice, established your diagnosis.

4. *Inability to function outside of a highly protective environment* means that you must avoid exposure to ultraviolet light (including sunlight passing through windows and light from similar unshielded light sources), wear protective clothing and eyeglasses, and use opaque broad-spectrum sunscreens in order to avoid skin cancer or other serious effects.

F. *How do we evaluate burns under 8.08?*

1. Electrical, chemical, or thermal burns frequently affect other body systems, for example, musculoskeletal, special senses and speech, respiratory, cardiovascular, genitourinary, neurological, or mental. We evaluate burns in the same way we evaluate

other disorders that can affect the skin and other body systems, using the listing for the predominant feature of your disorder. For example, if your soft tissue injuries resulting from burns are under surgical management (as defined in 8.00B6), we will evaluate your disorder under the listings in 1.00.

2. We evaluate burns resulting in chronic skin lesions (see 8.00B2) or contractures (see 8.00B3) that have been documented by an AMS to have reached maximum therapeutic benefit and therefore are no longer receiving surgical management, under 8.08. To be disabling, these burns must result in functional limitation(s) (see 8.00D2) that has lasted or can be expected to last for a continuous period of at least 12 months.

G. *How do we evaluate chronic conditions of the skin or mucous membranes under 8.09?* We evaluate skin disorders that result in chronic skin lesions (see 8.00B2) or contractures (see 8.00B3) under 8.09. These disorders must result in chronic skin lesions (see 8.00B2) or contractures (see 8.00B3) that continue to persist despite adherence to prescribed medical treatment for 3 months (see 8.00D5b) and cause functional limitations (see 8.00D2). Examples of skin disorders evaluated under this listing are ichthyosis, bullous diseases (such as pemphigus, epidermolysis bullosa, and dermatitis herpetiformis), chronic skin infections, dermatitis, psoriasis, and hidradenitis suppurativa.

H. *How do we evaluate disorders in other body systems that affect the skin?* When your disorder(s) in another body system affects your skin, we first evaluate the predominant feature of your disorder(s) under the appropriate body system. Examples of disorders in other body systems that may affect the skin include the following:

1. *Diabetes mellitus.* Diabetes mellitus that is not well controlled, despite treatment, can cause chronic hyperglycemia resulting in serious, long-lasting or recurrent exacerbations (see 8.00B7) or complications. We evaluate those exacerbations (see 8.00B7) or complications under the affected body system(s). If the complication involves soft tissue or amputation(s), we evaluate these features under the listings in 1.00. If the

exacerbations (see 8.00B7) or complications involve chronic bacterial or fungal skin lesions resulting from diabetes mellitus, we evaluate your limitations from the skin disorder under listing 8.09.

2. *Tuberous sclerosis.* The predominant functionally limiting features of tuberous sclerosis are seizures and intellectual disorder or other mental disorders. We evaluate these features under the listings in 11.00 or 12.00, as appropriate.

3. *Malignant tumors of the skin.* Malignant tumors of the skin (for example, malignant melanomas) are cancers, or malignant neoplastic diseases, that we evaluate under the listings in 13.00.

4. *Immune system disorders.* We evaluate skin manifestations of immune system disorders such as systemic lupus erythematosus, scleroderma, psoriasis, and human immunodeficiency virus (HIV) infection under the listings in 14.00.

5. *Head or facial disfigurement or deformity, and other physical deformities caused by skin disorders.* A head or facial disfigurement or deformity may result in loss of your sight, hearing, speech, or ability to chew. In addition to head and facial disfigurement and deformity, other physical deformities may result in associated psychological problems (for example, depression). We evaluate the effects of head or facial disfigurement or deformity, or other physical deformities caused by skin disorders under the listings in 1.00, 2.00, 5.00, or 12.00, as appropriate.

I. *How do we evaluate skin disorders that do not meet one of these listings?*

1. These listings are only examples of common skin disorders that we consider severe enough to prevent you from doing any gainful activity. If your impairment(s) does not meet the criteria of any of these listings, we must also consider whether you have an impairment(s) that satisfies the criteria of a listing in another body system.

2. If you have a severe medically determinable impairment(s) that does not meet a listing, we will determine whether your impairment(s) medically equals a listing. See §§

404.1526 and 416.926 of this chapter. If your impairment(s) does not meet or medically equal a listing, you may or may not have the residual functional capacity to engage in substantial gainful activity. We proceed to the fourth step and, if necessary, the fifth step of the sequential evaluation process in §§ 404.1520 and 416.920 of this chapter. We use the rules in §§ 404.1594 and 416.994 of this chapter, as appropriate, when we decide whether you continue to be disabled.

8.01 Category of Impairments, Skin Disorders

8.02–8.06 [Reserved]

8.07 *Genetic photosensitivity disorders*, established as described in 8.00E. The requirements of this listing are met if either paragraph A or paragraph B is satisfied.

A. Xeroderma pigmentosum (see 8.00E1).

OR

B. Other genetic photosensitivity disorders (see 8.00E2) with either 1 or 2:

1. Chronic skin lesions (see 8.00B2) or contractures (see 8.00B3) that cause an inability to function outside of a highly protective environment (see 8.00E4); or

2. Chronic skin lesions (see 8.00B2) or contractures (see 8.00B3) causing chronic pain or other physical limitation(s) that result in impairment-related functional limitations (see 8.00D2), as evidenced by:

a. Inability to use both upper extremities to the extent that neither can be used to independently initiate, sustain, and complete work-related activities involving fine and gross movements (see 8.00B5) due to chronic skin lesions (see 8.00B2) or contractures (see 8.00B3); or

b. Inability to use one upper extremity to independently initiate, sustain, and complete work-related activities involving fine and gross movements (see 8.00B5) due to chronic skin lesions (see 8.00B2) or contractures (see 8.00B3), and a documented

medical need (see 8.00B4) for an assistive device (see 8.00B1) that requires the use of the other upper extremity; or

c. Inability to stand up from a seated position and maintain an upright position to the extent needed to independently initiate, sustain, and complete work-related activities due to chronic skin lesions (see 8.00B2) or contractures (see 8.00B3) affecting at least two extremities (including when the limitations are due to involvement of the perineum or the inguinal region); or

d. Inability to maintain an upright position while standing or walking to the extent needed to independently initiate, sustain, and complete work-related activities, due to chronic skin lesions (see 8.00B2) or contractures (see 8.00B3) affecting both lower extremities (including when the limitations are due to involvement of the perineum or the inguinal region).

8.08 *Burns* (see 8.00F). Burns that do not require continuing surgical management (see 8.00B6), or that have been documented by an acceptable medical source to have reached maximum therapeutic benefit and therefore are no longer receiving surgical management, resulting in chronic skin lesions (see 8.00B2) or contractures (see 8.00B3) causing chronic pain or other physical limitation(s) that result in impairment-related functional limitations (see 8.00D2), as evidenced by:

A. Inability to use both upper extremities to the extent that neither can be used to independently initiate, sustain, and complete work-related activities involving fine and gross movements (see 8.00B5) due to chronic skin lesions (see 8.00B2) or contractures (see 8.00B3).

OR

B. Inability to use one upper extremity to independently initiate, sustain, and complete work-related activities involving fine and gross movements (see 8.00B5) due to chronic skin lesions (see 8.00B2) or contractures (see 8.00B3), and a documented

medical need (see 8.00B4) for an assistive device (see 8.00B1) that requires the use of the other upper extremity.

OR

C. Inability to stand up from a seated position and maintain an upright position to the extent needed to independently initiate, sustain, and complete work-related activities due to chronic skin lesions (see 8.00B2) or contractures (see 8.00B3) affecting at least two extremities (including when the limitations are due to involvement of the perineum or the inguinal region).

OR

D. Inability to maintain an upright position while standing or walking to the extent needed to independently initiate, sustain, and complete work-related activities due to chronic skin lesions (see 8.00B2) or contractures (see 8.00B3) affecting both lower extremities (including when the limitations are due to involvement of the perineum or the inguinal region).

8.09 *Chronic conditions of the skin or mucous membranes* (see 8.00G) resulting in:

A. Chronic skin lesions (see 8.00B2) or contractures (see 8.00B3) causing chronic pain or other physical limitation(s) that persist despite adherence to prescribed medical treatment for 3 months (see 8.00D5b).

AND

B. Impairment-related functional limitations (see 8.00D2) demonstrated by 1, 2, 3, or 4:

1. Inability to use both upper extremities to the extent that neither can be used to independently initiate, sustain, and complete work-related activities involving fine and gross movements (see 8.00B5) due to chronic skin lesions (see 8.00B2) or contractures (see 8.00B3); or

2. Inability to use one upper extremity to independently initiate, sustain, and complete work-related activities involving fine and gross movements (see 8.00B5) due to chronic skin lesions (see 8.00B2) or contractures (see 8.00B3), and a documented medical need (see 8.00B4) for an assistive device (see 8.00B1) that requires the use of the other upper extremity; or

3. Inability to stand up from a seated position and maintain an upright position to the extent needed to independently initiate, sustain, and complete work-related activities due to chronic skin lesions (see 8.00B2) or contractures (see 8.00B3) affecting at least two extremities (including when the limitations are due to involvement of the perineum or the inguinal region); or

4. Inability to maintain an upright position while standing or walking to the extent needed to independently initiate, sustain, and complete work-related activities due to chronic skin lesions (see 8.00B2) or contractures (see 8.00B3) affecting both lower extremities (including when the limitations are due to involvement of the perineum or the inguinal region).

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14.00 Immune System Disorders

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5. *Measurement of CD4 and either body mass index or hemoglobin (14.11G).* To evaluate your HIV infection under 14.11G, we require one measurement of your absolute CD4 count or your CD4 percentage, *and* either a measurement of your body mass index (BMI) or your hemoglobin. These measurements must occur within the period we are considering in connection with your application or continuing disability review. If you have more than one measurement of your CD4 (absolute count or percentage), BMI, or hemoglobin within this period, we will use the lowest of your CD4 (absolute count or

percentage), BMI, or hemoglobin. The date of your lowest CD4 (absolute count or percentage) measurement may be different from the date of your lowest BMI or hemoglobin measurement. We calculate your BMI using the formulas in the digestive disorders body system (5.00).

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Part B

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Sec.

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105.00 Digestive Disorders

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100.00 Low Birth Weight and Failure to Thrive

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c. BMI is the ratio of a child's weight to the square of his or her height. We calculate BMI using the formulas in the digestive disorders body system (105.00).

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103.00 Respiratory Disorders

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c. BMI is the ratio of a child's weight to the square of his or her height. We calculate BMI using the formulas in the digestive disorders body system (105.00).

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104.00 Cardiovascular System

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(iii) BMI is the ratio of a child's weight to the square of his or her height. We calculate BMI using the formulas in the digestive disorders body system (105.00).

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105.00 Digestive Disorders

A. *Which digestive disorders do we evaluate in this body system?* We evaluate digestive disorders that result in severe dysfunction of the liver, pancreas, and gastrointestinal tract (the large, muscular tube that extends from the mouth to the anus, where the movement of muscles, along with the release of hormones and enzymes, allows for the digestion of food) in this body system. Examples of these disorders and the listings we use to evaluate them include chronic liver disease (105.05), inflammatory bowel disease (105.06), and intestinal failure (105.07). We also use this body system to evaluate gastrointestinal hemorrhaging from any cause (105.02), growth failure due to any digestive disorder (105.08), liver transplantation (105.09), need for supplemental daily enteral feeding via a gastrostomy, duodenostomy, or jejunostomy due to any cause for children who have not attained age 3 (105.10), small intestine transplantation (105.11), and pancreas transplantation (105.12). We evaluate cancers affecting the digestive system under the listings in 113.00.

B. *What evidence do we need to evaluate your digestive disorder?*

1. *General.* To establish that you have a digestive disorder, we need medical evidence about the existence of your digestive disorder and its severity. Medical evidence should include your medical history, physical examination findings, operative reports, and relevant laboratory findings.

2. *Laboratory findings.* We need laboratory reports such as results of imaging (see 105.00B3), endoscopy, and other diagnostic procedures. We may also need clinical laboratory and pathology results.

3. *Imaging* refers to medical imaging techniques, such as x-ray, ultrasound, magnetic resonance imaging, and computerized tomography. The imaging must be consistent with the prevailing state of medical knowledge and clinical practice as a proper technique to support the evaluation of the disorder.

C. *What is chronic liver disease (CLD), and how do we evaluate it under 105.05?*

1. *General.* CLD is loss of liver function with cell necrosis (cell death), inflammation, or scarring of the liver that persists for more than 6 months. Common causes of CLD in children include chronic infection with hepatitis B virus or hepatitis C virus, autoimmune hepatitis, and metabolic disease.

a. We will evaluate your signs of CLD, such as jaundice, changes in size of the liver and spleen, ascites, peripheral edema, and altered mental status. We will also evaluate your symptoms of CLD, such as pruritus (itching), fatigue, nausea, loss of appetite, and sleep disturbances when we assess the severity of your impairment(s) and how it affects your ability to function. In the absence of evidence of a chronic liver impairment, episodes of acute liver disease do not meet the requirements of 105.05.

b. *Laboratory findings* of your CLD may include decreased serum albumin, increased International Normalized Ratio (INR), arterial deoxygenation (hypoxemia), increased serum creatinine, oliguria (reduced urine output), or sodium retention. Another laboratory finding that may be included in the evidence is a liver biopsy. If you have had a liver biopsy, we will make every reasonable effort to obtain the results; however, we will not purchase a liver biopsy.

2. *Manifestations of CLD.*

a. *Gastrointestinal hemorrhaging* (105.05A), as a consequence of cirrhosis and

high pressure in the liver's portal venous system, may occur from varices (dilated veins in the esophagus or the stomach) or from portal hypertensive gastropathy (abnormal mucosal changes in the stomach). When gastrointestinal hemorrhaging is due to a cause other than CLD, we evaluate it under 105.02. The phrase "consider under a disability for 1 year" in 105.02 and 105.05A does not refer to the date on which your disability began, only to the date on which we must reevaluate whether your impairment(s) continues to meet a listing or is otherwise disabling. We determine the onset of your disability based on the facts of your case.

b. *Ascites or hydrothorax* (105.05B) is a pathologic accumulation of fluid in the peritoneal cavity (ascites) or pleural space (hydrothorax). Ascites or hydrothorax may be diagnosed by removing some of the fluid with needle aspiration (paracentesis or thoracentesis), physical examination, or imaging. The most common causes of ascites are portal hypertension and low serum albumin resulting from CLD. We evaluate other causes of ascites and hydrothorax that are unrelated to CLD, such as congestive heart failure and cancer, under the listings in the affected body systems.

c. *Spontaneous bacterial peritonitis (SBP)* (105.05C) is an acute bacterial infection of peritoneal fluid and is most commonly associated with CLD. SBP is diagnosed by laboratory analysis of peritoneal fluid (obtained by paracentesis) that contains a neutrophil count (also called absolute neutrophil count) of at least 250 cells/mm^3. 105.05C is satisfied with one evaluation documenting peritoneal infection. We evaluate other causes of peritonitis that are unrelated to CLD, such as tuberculosis, malignancy, and perforated bowel, under the listings in the affected body systems.

d. *Hepatorenal syndrome* (105.05D) is renal failure associated with CLD in the absence of underlying kidney pathology. Findings associated with hepatorenal syndrome include elevation of serum creatinine, sodium retention with low urinary sodium excretion, and oliguria. We evaluate renal dysfunction with known underlying kidney

pathology, such as glomerulonephritis, tubular necrosis, and renal infections, under the listings in 106.00.

e. *Hepatopulmonary syndrome* (105.05E) is arterial deoxygenation due to intrapulmonary vascular dilation and arteriovenous shunting associated with CLD. Clinical findings of hepatopulmonary syndrome include platypnea (shortness of breath relieved when lying down) and orthodeoxia (low arterial blood oxygen while in the upright position), when presenting in the context of CLD. We evaluate pulmonary dysfunction with known underlying respiratory pathology, such as asthma, pneumonia, and pulmonary infections, under the listings in 103.00.

(i) Under 105.05E1, we require a resting arterial blood gas (ABG) measurement obtained while you are breathing room air; that is, without oxygen supplementation. The ABG report must include the P_aO_2 value, your name, the date of the test, and either the altitude or both the city and State of the test site.

(ii) We will not purchase the specialized imaging techniques described in 105.05E2; however, if you have had the test(s) at a time relevant to your claim, we will make every reasonable effort to obtain the report.

f. *Hepatic encephalopathy* (105.05F), also known as portosystemic encephalopathy, is a recurrent or chronic neuropsychiatric disorder associated with CLD.

(i) Under 105.05F2, we require documentation of a mental impairment associated with hepatic encephalopathy. A mental impairment can include abnormal behavior, changes in mental status, or an altered state of consciousness. Reports of abnormal behavior may show that you are experiencing delusions, paranoia, or hallucinations. Reports of changes in mental status may show change in sleep patterns, personality or mood changes, poor concentration, or poor judgment or cognitive dysfunction (for example, impaired memory, poor problem-solving ability, or attention deficits). Reports of altered state of consciousness may show that you are experiencing confusion, delirium,

or stupor.

(ii) Signs and laboratory findings that document the severity of hepatic encephalopathy when not attributable to other causes may include a "flapping tremor" (asterixis), characteristic abnormalities found on an electroencephalogram (EEG), or abnormal serum albumin or coagulation values. We will not purchase an EEG; however, if you have had this test at a time relevant to your claim, we will make every reasonable effort to obtain the report for the purpose of establishing whether your impairment meets the criteria of 105.05F.

(iii) We will not evaluate acute encephalopathy under 105.05F if it results from conditions other than CLD. For example, we will evaluate acute encephalopathy caused by vascular events under the listings in 111.00 and acute encephalopathy caused by cancer under the listings in 113.00.

3. *SSA Chronic Liver Disease (SSA CLD) and SSA Chronic Liver Disease-Pediatric (SSA CLD-P) scores* (105.05G). Listing 105.05G1 requires two SSA CLD scores, each requiring three or four laboratory values. Listing 105.05G2 requires one SSA CLD-P score, which requires four parameters (three laboratory values and growth failure). The "date of the SSA CLD score" is the date of the earliest of the three or four laboratory values used for its calculation. The "date of the SSA CLD-P score" is the date of the earliest of the three laboratory values used for its calculation. For 105.05G1, the date of the second SSA CLD score must be at least 60 days after the date of the first SSA CLD score and both scores must be within the required 12-month period. If you have the two SSA CLD scores required by 105.05G1, we will find that your impairment meets the criteria of the listing from at least the date of the first SSA CLD score.

a. *SSA CLD score.*

(i) If you are age 12 or older, we will calculate the SSA CLD score using a formula that includes up to four laboratory values: Serum creatinine (mg/dL), total

bilirubin (mg/dL), INR, and under certain conditions, serum sodium (mmol/L). The SSA CLD score calculation contains at least one, and sometimes two, parts, as described in (a) and (b).

(a) The initial calculation is:

$$\text{SSA CLD}_i = 9.57 \times [\log_e(\text{serum creatinine mg/dL})] + 3.78 \times [\log_e(\text{serum total bilirubin mg/dL})] + 11.2 \times [\log_e(\text{INR})] + 6.43$$

rounded to the nearest whole integer.

(b) If the value from the initial calculation is 11 or below, the SSA CLD score will be the SSA CLD_i value. If the value from the initial calculation is greater than 11, the SSA CLD score will be re-calculated as:

$$\text{SSA CLD} = \text{SSA CLD}_i + 1.32 \times (137 - \text{serum sodium mmol/L}) - [0.033 \times \text{SSA CLD}_i \times (137 - \text{serum sodium mmol/L})]$$

(c) We round the results of your SSA CLD score calculation to the nearest whole integer to arrive at your SSA CLD score.

(ii) For any SSA CLD score calculation, all of the required laboratory values (serum creatinine, serum total bilirubin, INR, and serum sodium) must have been obtained within a continuous 30-day period.

(a) We round values for serum creatinine (mg/dL), serum total bilirubin (mg/dL), or INR less than 1.0 up to 1.0 to calculate your SSA CLD score.

(b) We round values for serum creatinine (mg/dL) greater than 4.0 down to 4.0 to calculate your SSA CLD score.

(c) If there are multiple laboratory values within the 30-day interval for serum creatinine (mg/dL), serum total bilirubin (mg/dL), or INR, we use the *highest* value to calculate your SSA CLD score. We will not use any INR values derived from testing

done while you are on anticoagulant treatment in our SSA CLD calculation.

(d) If there are multiple laboratory values within the 30-day interval for serum sodium (mmol/L), we use the *lowest* value to calculate your SSA CLD score.

(e) If you are in renal failure or on renal dialysis within a week of any serum creatinine test in the period used for the SSA CLD calculation, we will use a serum creatinine value of 4.0, which is the maximum serum creatinine level allowed in the calculation, to calculate your SSA CLD score.

(f) If your serum sodium is less than 125 mmol/L, we will set your serum sodium to 125 mmol/L for purposes of calculation of the SSA CLD score. If your serum sodium is higher than 137 mmol/L, we will set your serum sodium to 137 mmol/L for purposes of calculation of the SSA CLD score.

(iii) When we indicate "$\log_e$" (also abbreviated "ln") in the formula for the SSA CLD score calculation, we mean the "base e logarithm" or "natural logarithm" of the numerical laboratory value, not the "base 10 logarithm" or "common logarithm" (log) of the laboratory value, and not the actual laboratory value. For example, if a person has laboratory values of serum creatinine 1.4 mg/dL, serum total bilirubin 1.3 mg/dL, INR 1.32, and serum sodium 119 mmol/L, we compute the SSA CLD score as follows:

$$
\begin{aligned}
&\text{SSA CLD}_i = \\
&9.57 \times [\log_e(\text{serum creatinine 1.4 mg/dL}) = 0.336] \\
&+ 3.78 \times [\log_e(\text{serum total bilirubin 1.3 mg/dL}) = 0.262] \\
&+ 11.2 \times [\log_e(\text{INR 1.32}) = .278] \\
&+ 6.43 \\
&= 3.22 + 0.99 + 3.11 + 6.43 \\
&= 13.75, \text{ which we round to an SSA CLD}_i \text{ score of 14.}
\end{aligned}
$$

Because the SSA CLD_i score is over 11, we then move to the second step of calculating the SSA CLD:

$$
\begin{aligned}
&\text{SSA CLD} = \\
&14 \\
&+ 1.32 \times (137 - \text{serum sodium 125 mmol/L}) \\
&- [0.033 \times \text{SSA CLD}_i\ 14 \times (137 - \text{serum sodium 125 mmol/L}) \\
&= 14 + 15.84 - 5.54
\end{aligned}
$$

= 24.3, which we round to an SSA CLD score of 24.

b. *SSA CLD-P score*

(i) We calculate the SSA CLD-P score using a formula that includes four parameters: Serum total bilirubin (mg/dL), INR, serum albumin (g/dL), and whether you have growth failure. The formula for the SSA CLD-P score calculation is:

$4.80 \times [\log_e(\text{serum total bilirubin mg/dL})]$
$+ 18.57 \times [\log_e(\text{INR})]$
$- 6.87 \times [\log_e(\text{serum albumin g/dL})]$
$+ 6.67$ if you have growth failure (<-2 standard deviations for weight or height)

(ii) When we indicate "$\log_e$" in the formula for the SSA CLD-P score calculation, we mean the "base *e* logarithm" or "natural logarithm" ($\log_e$) of a numerical laboratory value, not the "base 10 logarithm" or "common logarithm" (log) of the laboratory value, and not the actual laboratory value. For example, if a female child is 4.0 years old, has growth failure, and has laboratory values of serum total bilirubin 2.2 mg/dL, INR 1.0, and serum albumin 3.5 g/dL, we compute the SSA CLD-P score as follows:

$4.80 \times [\log_e(\text{serum total bilirubin 2.2 mg/dL}) = 0.788]$
$+ 18.57 \times [\log_e(\text{INR 1.0}) = 0]$
$- 6.87 \times [\log_e(\text{serum albumin 3.5 g/dL}) = 1.253]$
$+ 6.67$
$= 3.78 + 0 - 8.61 + 6.67$
$= 1.84$, which we round to an SSA CLD-P score of 2.

(iii) For an SSA CLD-P score calculation, all of the required laboratory values (serum total bilirubin, INR, and serum albumin) must have been obtained within a continuous 30-day period. We round any of the required laboratory values less than 1.0 up to 1.0 to calculate your SSA CLD-P score. If there are multiple laboratory values within the 30-day interval for any given laboratory test, we use the *highest* serum total bilirubin and INR values and the *lowest* serum albumin value to calculate the SSA CLD-P score. We will not use any INR values derived from testing done while you are on anticoagulant treatment in our SSA CLD-P calculation. We will not purchase INR values for children who have not attained age 12. If there is no INR value for a child under 12

within the applicable period, we will use an INR value of 1.1 to calculate the SSA CLD-P score. We round the results of your SSA CLD-P score calculation to the nearest whole integer to arrive at your SSA CLD-P score.

(iv) The weight and length/height measurements used for the calculation must be obtained within the same 30-day period as the laboratory values.

4. *Extrahepatic biliary atresia* (105.05H) presents itself in the first 2 months of life with persistent jaundice. To satisfy 105.05H, the diagnosis of extrahepatic biliary atresia must be confirmed by liver biopsy or intraoperative cholangiogram that shows obliteration of the extrahepatic biliary tree. Biliary atresia is usually treated surgically by portoenterostomy (for example, Kasai procedure). If this surgery is not performed in the first months of life or is not completely successful, liver transplantation is indicated. If you have received a liver transplant, we will evaluate your impairment under 105.09. The phrase "consider under a disability for 1 year" in 105.05H does not refer to the date on which your disability began, only to the date on which we must reevaluate whether your impairment(s) continues to meet a listing or is otherwise disabling. We determine the onset of your disability based on the facts of your case.

D. *What is inflammatory bowel disease (IBD), and how do we evaluate it under 105.06?*

1. *IBD* is a group of inflammatory conditions of the small intestine and colon. The most common IBD disorders are Crohn's disease and ulcerative colitis. Remissions and exacerbations of variable duration are a hallmark of IBD.

2. We evaluate your signs and symptoms of IBD, such as diarrhea, fecal incontinence, rectal bleeding, abdominal pain, fatigue, fever, nausea, vomiting, arthralgia, abdominal tenderness, palpable abdominal mass (usually inflamed loops of bowel), and perianal disease (for example, fissure, fistulas, abscesses, or anal canal stenosis), when we assess the severity of your impairment(s). You may require supplemental daily

nutrition due to IBD. There are two forms of supplemental daily nutrition we consider under 105.06B5: enteral nutrition (delivered directly to a part of your digestive system) via a gastrostomy, duodenostomy, or jejunostomy, and parenteral nutrition delivered via a central venous catheter. Enteral tube feedings delivered via nasal or oral tubes do not satisfy the requirement in 105.06B5.

3. Surgical diversion of the intestinal tract, including ileostomy and colostomy, does not very seriously interfere with age-appropriate functioning if you are able to maintain adequate nutrition and function of the stoma. However, if you are not able to maintain adequate nutrition, we will evaluate your impairment under 105.08.

4. IBD may be associated with significant extraintestinal manifestations in a variety of body systems. These include, but are not limited to, involvement of the eye (for example, uveitis, episcleritis, or iritis); hepatobiliary disease (for example, gallstones or primary sclerosing cholangitis); urologic disease (for example, kidney stones or obstructive hydronephrosis); skin involvement (for example, erythema nodosum or pyoderma gangrenosum); or non-destructive inflammatory arthritis. You may also have associated thromboembolic disorders or vascular disease. These manifestations may not correlate with the severity of your IBD. If your impairment does not meet any of the criteria of 105.06, we will consider the effects of your extraintestinal manifestations in determining whether you have an impairment(s) that meets or medically equals another listing, and when we determine whether your impairment(s) functionally equals the listings.

5. Examples of complications of IBD that may result in hospitalization include abscesses, intestinal perforation, toxic megacolon, infectious colitis, pyoderma gangrenosum, ureteral obstruction, primary sclerosing cholangitis, and hypercoagulable state (which may lead to thromboses or embolism).

E. *What is intestinal failure, and how do we evaluate it under 105.07?*

1. *Intestinal failure* is a condition resulting in gut function below the minimum necessary for the absorption of macronutrients or water and electrolytes, resulting in a requirement for intravenous supplementation (i.e., parenteral nutrition) to maintain health. Examples of conditions that may result in intestinal failure include short bowel syndrome, extensive small bowel mucosal disease, and chronic motility disorders.

2. *Short bowel syndrome* is a malabsorption disorder that occurs when ischemic vascular insults (caused, for example, by volvulus or necrotizing enterocolitis), trauma, or IBD complications require(s) surgical resection of any amount of the small intestine, resulting in chronic malnutrition.

3. *Extensive small bowel mucosal disease* means that the mucosal surface of the small bowel does not efficiently absorb nutrients or loses nutrients. Common causes of small bowel mucosal disease include microvillous inclusion disease and tufting enteropathy.

4. *Chronic motility disorder* refers to a chronic disorder of the propulsion of gut content without fixed obstructions, causing intolerance to oral nutrition and inadequate nutritional intake. This type of disorder may also be known as a chronic intestinal pseudo-obstruction (CIPO), because the gut dysfunction mimics that of an obstructed intestine, but without evidence of an actual obstruction. Primary CIPO may have an unknown underlying cause. Chronic motility disorders may also result from congenital, neuromuscular, or autoimmune conditions, such as gastroschisis, omphalocele, long segment Hirschprung's disease, Crohn's disease, and mitochondrial disorders.

5. For short bowel syndrome, we require a copy of the operative report that includes details of the surgical findings, or postoperative imaging indicating a resection of the small intestine. If we cannot get one of these reports, we need other medical reports that include details of the surgical findings. For other chronic motility disorders or extensive small bowel mucosal disease, we need medical reports that include details of

your intestinal dysfunction. For any impairment evaluated under 105.07, we also need medical documentation that you are dependent on daily parenteral nutrition to provide most of your nutritional requirements.

F. *How do we evaluate growth failure due to any digestive disorder under 105.08?*

1. To evaluate growth failure due to any digestive disorder, we require documentation of the laboratory findings of chronic nutritional deficiency described in 105.08A and the growth measurements in 105.08B within the same consecutive 12-month period. The dates of laboratory findings may be different from the dates of growth measurements. Impairments other than digestive disorders that cause weight loss should be evaluated under the appropriate body system. For instance, weight loss as a result of chronic kidney disease should be evaluated under our rules for genitourinary disorders (see 106.00), and weight loss as the result of an eating disorder should be evaluated under our rules for mental disorders (see 112.00). However, if you develop a digestive disorder as the result of your other impairment, we will evaluate the acquired digestive disorder under our rules for digestive disorders.

2. Under 105.08B, we evaluate a child's growth failure by using the appropriate table for age and gender.

a. For children from birth to attainment of age 2, we use the weight-for-length table (see Table I or Table II).

b. For children age 2 to attainment of age 18, we use the body mass index (BMI)-for-age table (see Table III or Table IV).

c. BMI is the ratio of your weight to the square of your height. We calculate BMI using one of the following formulas:

English Formula

BMI = [Weight in Pounds / (Height in Inches × Height in Inches)] × 703

Metric Formulas

BMI = Weight in Kilograms / (Height in Meters × Height in Meters)

BMI = [Weight in Kilograms / (Height in Centimeters × Height in Centimeters)] × 10,000

G. *How do we evaluate digestive organ transplantation?* If you receive a liver (105.09), small intestine (105.11), or pancreas (105.12) transplant, we will consider you disabled under the listing for 1 year from the date of the transplant. After that, we evaluate your residual impairment(s) by considering the adequacy of your post-transplant function, the frequency and severity of any rejection episodes you have, complications in other body systems, and adverse treatment effects. People who receive digestive organ transplants generally have impairments that meet our definition of disability before they undergo transplantation. The phrase "consider under a disability for 1 year" in 105.09, 105.11, and 105.12 does not refer to the date on which your disability began, only to the date on which we must reevaluate whether your impairment(s) continues to meet a listing or is otherwise disabling. We determine the onset of your disability based on the facts of your case.

H. *How do we evaluate the need for supplemental daily enteral feeding via a gastrostomy, duodenostomy, or jejunostomy?* We evaluate the need for supplemental daily enteral feeding via a gastrostomy, duodenostomy, or jejunostomy in children who have not attained age 3 under 105.10 regardless of the medical reason for the stoma. Enteral tube feedings delivered via nasal or oral tubes do not satisfy the requirement in 105.10. After a child attains age 3, we evaluate growth failure due to any digestive disorder under 105.08, IBD requiring supplemental daily enteral or parenteral nutrition under 105.06, or other medical or developmental disorders under another digestive disorders listing or under a listing in an affected body system(s).

I. *How do we evaluate esophageal stricture or stenosis?* Esophageal stricture or

stenosis (narrowing) from congenital atresia (absence or abnormal closure of a tubular body organ) or destructive esophagitis may result in malnutrition or the need for gastrostomy placement, which we evaluate under 105.08 or 105.10. Esophageal stricture or stenosis may also result in complications such as pneumonias due to frequent aspiration, or difficulty in maintaining nutritional status short of listing level severity. While these individual complications usually do not meet the listing criteria, a combination of your impairments may medically equal a listing or functionally equal the listings.

J. *How do we evaluate your digestive disorder if there is no record of ongoing treatment?* If there is no record of ongoing treatment despite the existence of a severe impairment(s), we will assess the severity and duration of your digestive disorder based on the current medical and other evidence in your case record. If there is no record of ongoing treatment, you may not be able to show an impairment that meets a digestive disorders listing, but your impairment may medically equal a listing, or be disabling based on our rules for functional equivalence.

K. *How do we evaluate your digestive disorder if there is evidence establishing a substance use disorder?* If we find that you are disabled and there is medical evidence in your case record establishing that you have a substance use disorder, we will determine whether your substance use disorder is a contributing factor material to the determination of disability. See § 416.935 of this chapter. Digestive disorders resulting from drug or alcohol use are often chronic in nature and will not necessarily improve with cessation in drug or alcohol use.

L. *How do we evaluate digestive disorders that do not meet one of these listings?*

1. These listings are only examples of common digestive disorders that we consider severe enough to result in marked and severe functional limitations. If your impairment(s) does not meet the criteria of any of these listings, we must also consider

whether you have an impairment(s) that satisfies the criteria of a listing in another body system.

2. If you have a severe medically determinable impairment(s) that does not meet a listing, we will determine whether your impairment(s) medically equals a listing. See § 416.926 of this chapter. Digestive disorders may be associated with disorders in other body systems, and we consider the combined effects of multiple impairments when we determine whether they medically equal a listing. If your impairment(s) does not meet or medically equal a listing, we will also consider whether it functionally equals the listings. See § 416.926a of this chapter. We use the rules in § 416.994a of this chapter when we decide whether you continue to be disabled.

105.01 Category of Impairments, Digestive Disorders

105.02 *Gastrointestinal hemorrhaging from any cause, requiring three blood transfusions* of at least 10 cc of blood/kg of body weight per transfusion, within a consecutive 12-month period and at least 30 days apart. Consider under a disability for 1 year following the last documented transfusion; after that, evaluate the residual impairment(s).

105.03–105.04 [Reserved]

105.05 *Chronic liver disease (CLD)* (see 105.00C) with A, B, C, D, E, F, G, or H:

A. Hemorrhaging from esophageal, gastric, or ectopic varices, or from portal hypertensive gastropathy (see 105.00C2a), documented by imaging (see 105.00B3); resulting in 1 and 2:

1. Hemodynamic instability indicated by signs such as pallor (pale skin), diaphoresis (profuse perspiration), rapid pulse, low blood pressure, postural hypotension (pronounced fall in blood pressure when arising to an upright position from lying down), or syncope (fainting); and

2. Requiring hospitalization for transfusion of at least 10 cc of blood/kg of body

weight. Consider under a disability for 1 year following the documented transfusion; after that, evaluate the residual impairment(s).

OR

B. Ascites or hydrothorax not attributable to other causes (see 105.00C2b), present on two evaluations within a consecutive 12-month period and at least 60 days apart. Each evaluation must document the ascites or hydrothorax by 1, 2, or 3:

1. Paracentesis; or

2. Thoracentesis; or

3. Imaging or physical examination with a or b:

a. Serum albumin of 3.0 g/dL or less; or

b. INR of at least 1.5.

OR

C. Spontaneous bacterial peritonitis (see 105.00C2c) documented by peritoneal fluid containing a neutrophil count of at least 250 cells/mm^3.

OR

D. Hepatorenal syndrome (see 105.00C2d) documented by 1, 2, or 3:

1. Serum creatinine elevation of at least 2 mg/dL; or

2. Oliguria with 24-hour urine output less than 1 mL/kg/hr; or

3. Sodium retention with urine sodium less than 10 mEq per liter.

OR

E. Hepatopulmonary syndrome (see 105.00C2e) documented by 1 or 2:

1. Arterial P_aO_2 measured by an ABG test, while at rest, breathing room air, less than or equal to:

a. 60 mm Hg, at test sites less than 3,000 feet above sea level; or

b. 55 mm Hg, at test sites from 3,000 through 6,000 feet above sea level; or

c. 50 mm Hg, at test sites over 6,000 feet above sea level; or

2. Intrapulmonary arteriovenous shunting as shown on contrast-enhanced echocardiography or macroaggregated albumin lung perfusion scan.

OR

F. Hepatic encephalopathy (see 105.00C2f) with documentation of abnormal behavior, cognitive dysfunction, changes in mental status, or altered state of consciousness (for example, confusion, delirium, stupor, or coma), present on two evaluations within a consecutive 12-month period and at least 60 days apart and either 1 or 2:

1. History of transjugular intrahepatic portosystemic shunt (TIPS) or other surgical portosystemic shunt; or

2. One of the following on at least two evaluations at least 60 days apart within the same consecutive 12-month period as in F:

a. Asterixis or other fluctuating physical neurological abnormalities; or

b. EEG demonstrating triphasic slow wave activity; or

c. Serum albumin of 3.0 g/dL or less; or

d. INR of 1.5 or greater.

OR

G. SSA CLD or SSA CLD-P scores (see 105.00C3):

1. For children age 12 or older, two SSA CLD scores of at least 20 within a consecutive 12-month period and at least 60 days apart. Consider under a disability from at least the date of the first score; or

2. For children who have not attained age 12, one SSA CLD-P score of at least 11.

OR

H. Extrahepatic biliary atresia as diagnosed on liver biopsy or intraoperative cholangiogram (see 105.00C4). Consider under a disability for 1 year following

diagnosis; after that, evaluate the residual impairment(s).

105.06 *Inflammatory bowel disease (IBD)* (see 105.00D) documented by endoscopy, biopsy, imaging, or operative findings *and* demonstrated by A or B:

A. Obstruction of stenotic areas (not adhesions) in the small intestine or colon with proximal dilatation, confirmed by imaging or in surgery, requiring two hospitalizations for intestinal decompression or for surgery, within a consecutive 12-month period and at least 60 days apart.

OR

B. Two of the following occurring within a consecutive 12-month period and at least 60 days apart:

1. Anemia with hemoglobin less than 10.0 g/dL, present on at least two evaluations at least 60 days apart; or

2. Serum albumin of 3.0 g/dL or less, present on at least two evaluations at least 60 days apart; or

3. Clinically documented tender abdominal mass palpable on physical examination with abdominal pain or cramping; or

4. Perianal disease with a draining abscess or fistula; or

5. Need for supplemental daily enteral nutrition via a gastrostomy, duodenostomy, or jejunostomy, or daily parenteral nutrition via a central venous catheter (see 105.10 for children who have not attained age 3).

105.07 *Intestinal failure* (see 105.00E) due to short bowel syndrome, chronic motility disorders, or extensive small bowel mucosal disease, resulting in dependence on daily parenteral nutrition via a central venous catheter for at least 12 months.

105.08 *Growth failure due to any digestive disorder* (see 105.00F), documented by A and B:

A. Chronic nutritional deficiency present on two evaluations within a consecutive

12-month period and at least 60 days apart documented by 1 or 2:

1. Anemia with hemoglobin less than 10.0 g/dL; or

2. Serum albumin of 3.0 g/dL or less.

AND

B. Growth failure as required in 1 or 2:

1. *For children from birth to attainment of age 2*, three weight-for-length measurements that are:

a. Within a consecutive 12-month period; and

b. At least 60 days apart; and

c. Less than the third percentile values in Table I or Table II; or

Table I - Males Birth to Attainment of Age 2

Third Percentile Values for Weight-for-Length

Length (centimeters)	Weight (kilograms)	Length (centimeters)	Weight (kilograms)	Length (centimeters)	Weight (kilograms)
45.0	1.597	64.5	6.132	84.5	10.301
45.5	1.703	65.5	6.359	85.5	10.499
46.5	1.919	66.5	6.584	86.5	10.696
47.5	2.139	67.5	6.807	87.5	10.895
48.5	2.364	68.5	7.027	88.5	11.095
49.5	2.592	69.5	7.245	89.5	11.296
50.5	2.824	70.5	7.461	90.5	11.498
51.5	3.058	71.5	7.674	91.5	11.703
52.5	3.294	72.5	7.885	92.5	11.910
53.5	3.532	73.5	8.094	93.5	12.119
54.5	3.771	74.5	8.301	94.5	12.331
55.5	4.010	75.5	8.507	95.5	12.546
56.5	4.250	76.5	8.710	96.5	12.764
57.5	4.489	77.5	8.913	97.5	12.987
58.5	4.728	78.5	9.113	98.5	13.213
59.5	4.966	79.5	9.313	99.5	13.443
60.5	5.203	80.5	9.512	100.5	13.678
61.5	5.438	81.5	9.710	101.5	13.918
62.5	5.671	82.5	9.907	102.5	14.163
63.5	5.903	83.5	10.104	103.5	14.413

Table II- Females Birth to Attainment of Age 2

Third Percentile Values for Weight-for-Length

Length (centimeters)	Weight (kilograms)	Length (centimeters)	Weight (kilograms)	Length (centimeters)	Weight (kilograms)
45.0	1.613	64.5	5.985	84.5	10.071
45.5	1.724	65.5	6.200	85.5	10.270
46.5	1.946	66.5	6.413	86.5	10.469
47.5	2.171	67.5	6.625	87.5	10.670
48.5	2.397	68.5	6.836	88.5	10.871
49.5	2.624	69.5	7.046	89.5	11.074
50.5	2.852	70.5	7.254	90.5	11.278
51.5	3.081	71.5	7.461	91.5	11.484
52.5	3.310	72.5	7.667	92.5	11.691
53.5	3.538	73.5	7.871	93.5	11.901
54.5	3.767	74.5	8.075	94.5	12.112
55.5	3.994	75.5	8.277	95.5	12.326
56.5	4.220	76.5	8.479	96.5	12.541
57.5	4.445	77.5	8.679	97.5	12.760
58.5	4.669	78.5	8.879	98.5	12.981
59.5	4.892	79.5	9.078	99.5	13.205
60.5	5.113	80.5	9.277	100.5	13.431
61.5	5.333	81.5	9.476	101.5	13.661
62.5	5.552	82.5	9.674	102.5	13.895
63.5	5.769	83.5	9.872	103.5	14.132

2. *For children age 2 to attainment of age 18*, three BMI-for-age measurements that are:

a. Within a consecutive 12-month period; and

b. At least 60 days apart; and

c. Less than the third percentile value in Table III or Table IV.

Table III - Males Age 2 to Attainment of Age 18

Third Percentile Values for BMI-for-Age

Age (yrs. and mos.)	BMI	Age (yrs. and mos.)	BMI	Age (yrs. and mos.)	BMI
2.0 to 2.1	14.5	10.11 to 11.2	14.3	14.9 to 14.10	16.1
2.2 to 2.4	14.4	11.3 to 11.5	14.4	14.11 to 15.0	16.2
2.5 to 2.7	14.3	11.6 to 11.8	14.5	15.1 to 15.3	16.3
2.8 to 2.11	14.2	11.9 to 11.11	14.6	15.4 to 15.5	16.4
3.0 to 3.2	14.1	12.0 to 12.1	14.7	15.6 to 15.7	16.5
3.3 to 3.6	14.0	12.2 to 12.4	14.8	15.8 to 15.9	16.6
3.7 to 3.11	13.9	12.5 to 12.7	14.9	15.10 to 15.11	16.7
4.0 to 4.5	13.8	12.8 to 12.9	15.0	16.0 to 16.1	16.8
4.6 to 5.0	13.7	12.10 to 13.0	15.1	16.2 to 16.3	16.9
5.1 to 6.0	13.6	13.1 to 13.2	15.2	16.4 to 16.5	17.0

6.1 to 7.6	13.5	13.3 to 13.4	15.3	16.6 to 16.8	17.1
7.7 to 8.6	13.6	13.5 to 13.7	15.4	16.9 to 16.10	17.2
8.7 to 9.1	13.7	13.8 to 13.9	15.5	16.11 to 17.0	17.3
9.2 to 9.6	13.8	13.10 to 13.11	15.6	17.1 to 17.2	17.4
9.7 to 9.11	13.9	14.0 to 14.1	15.7	17.3 to 17.5	17.5
10.0 to 10.3	14.0	14.2 to 14.4	15.8	17.6 to 17.7	17.6
10.4 to 10.7	14.1	14.5 to 14.6	15.9	17.8 to 17.9	17.7
10.8 to 10.10	14.2	14.7 to 14.8	16.0	17.10 to 17.11	17.8

Table IV - Females Age 2 to Attainment of Age 18

Third Percentile Values for BMI-for-Age

Age (yrs. and mos.)	BMI	Age (yrs. and mos.)	BMI	Age (yrs. and mos.)	BMI
2.0 to 2.2	14.1	10.8 to 10.10	14.0	14.3 to 14.5	15.6
2.3 to 2.6	14.0	10.11 to 11.2	14.1	14.6 to 14.7	15.7
2.7 to 2.10	13.9	11.3 to 11.5	14.2	14.8 to 14.9	15.8
2.11 to 3.2	13.8	11.6 to 11.7	14.3	14.10 to 15.0	15.9
3.3 to 3.6	13.7	11.8 to 11.10	14.4	15.1 to 15.2	16.0
3.7 to 3.11	13.6	11.11 to 12.1	14.5	15.3 to 15.5	16.1
4.0 to 4.4	13.5	12.2 to 12.4	14.6	15.6 to 15.7	16.2
4.5 to 4.11	13.4	12.5 to 12.6	14.7	15.8 to 15.10	16.3
5.0 to 5.9	13.3	12.7 to 12.9	14.8	15.11 to 16.0	16.4
5.10 to 7.6	13.2	12.10 to 12.11	14.9	16.1 to 16.3	16.5
7.7 to 8.4	13.3	13.0 to 13.2	15.0	16.4 to 16.6	16.6
8.5 to 8.10	13.4	13.3 to 13.4	15.1	16.7 to 16.9	16.7
8.11 to 9.3	13.5	13.5 to 13.7	15.2	16.10 to 17.0	16.8
9.4 to 9.8	13.6	13.8 to 13.9	15.3	17.1 to 17.3	16.9
9.9 to 10.0	13.7	13.10 to 14.0	15.4	17.4 to 17.7	17.0
10.1 to 10.4	13.8	14.1 to 14.2	15.5	17.8 to 17.11	17.1
10.5 to 10.7	13.9				

105.09 *Liver transplantation* (see 105.00G). Consider under a disability for 1 year from the date of the transplant; after that, evaluate the residual impairment(s).

105.10 *Need for supplemental daily enteral feeding via a gastrostomy, duodenostomy, or jejunostomy* (see 105.00H) due to any cause, for children who have not attained age 3; after that, evaluate the residual impairment(s).

105.11 *Small intestine transplantation* (see 105.00G). Consider under a disability for 1 year from the date of the transplant; after that, evaluate the residual impairment(s).

105.12 *Pancreas transplantation* (see 105.00G). Consider under a disability for 1 year from the date of the transplant; after that, evaluate the residual impairment(s).

106.00 Genitourinary Disorders

C. * * *

5. * * *

b. * * *

(iii) BMI is the ratio of a child's weight to the square of his or her height. We calculate BMI using the formulas in the digestive disorders body system (105.00).

* * * * *

108.00 Skin Disorders

A. *Which skin disorders do we evaluate under these listings?* We use these listings to evaluate skin disorders that result from hereditary, congenital, or acquired pathological processes. We evaluate genetic photosensitivity disorders (108.07), burns (108.08), and chronic conditions of the skin or mucous membranes such as ichthyosis, bullous disease, dermatitis, psoriasis, and hidradenitis suppurativa (108.09) under these listings.

B. *What are our definitions for the following terms used in this body system?*

1. *Assistive device(s):* An assistive device, for the purposes of these listings, is any device used to improve stability, dexterity, or mobility. An assistive device can be hand-held, such as a cane(s), a crutch(es), or a walker; used in a seated position, such as a wheelchair, rollator, or power operated vehicle; or worn, such as a prosthesis or an orthosis.

2. *Chronic skin lesions:* Chronic skin lesions can have recurrent exacerbations (see 108.00B7). They can occur despite prescribed medical treatment. These chronic skin lesions can develop on any part of your body, including upper extremities, lower extremities, palms of your hands, soles of your feet, the perineum, inguinal (groin)

region, and axillae (underarms). Chronic skin lesions may result in functional limitations as described in 108.00D2.

3. *Contractures:* Contractures are permanent fibrous scar tissue resulting in tightening and thickening of skin that prevents normal movement of the damaged area. They can develop on any part of your musculoskeletal system, including upper extremities, lower extremities, palms of your hands, soles of your feet, the perineum, inguinal (groin) region, and axillae (underarms). Contractures may result in functional limitations as described in 108.00D2.

4. *Documented medical need:* When we use the term "documented medical need," we mean that there is evidence (see § 416.913 of this chapter) from your medical source(s) in the medical record that supports your need for an assistive device (see 108.00B1) for a continuous period of at least 12 months. The evidence must include documentation from your medical source(s) describing any limitation(s) in your upper or lower extremity functioning that supports your need for the assistive device and describing the circumstances for which you need it. The evidence does not have to include a specific prescription for the device.

5. *Fine and gross movements:* Fine movements, for the purposes of these listings, involve use of your wrists, hands, and fingers; such movements include picking, pinching, manipulating, and fingering. Gross movements involve use of your shoulders, upper arms, forearms, and hands; such movements include handling, gripping, grasping, holding, turning, and reaching. Gross movements also include exertional activities such as lifting, carrying, pushing, and pulling. Evaluation of fine and gross movements is dependent on your age.

6. *Surgical management:* For the purposes of these listings, surgical management includes the surgery(ies) itself, as well as various post-surgical procedures, surgical

complications, infections or other medical complications, related illnesses, or related treatments that delay a person's attainment of maximum benefit from surgery.

7. *Exacerbation:* For the purposes of these listings, exacerbation means an increase in the signs or symptoms of the skin disorder. Exacerbation may also be referred to as flare, flare-up, or worsening of the skin disorder.

C. *What evidence do we need to evaluate your skin disorder?*

1. To establish the presence of a skin disorder as a medically determinable impairment, we need objective medical evidence from an acceptable medical source (AMS) who has examined you for the disorder.

2. We will make every reasonable effort to obtain your medical history, treatment records, and relevant laboratory findings, but we will not purchase genetic testing.

3. When we evaluate the presence and severity of your skin disorder(s), we generally need information regarding:

a. The onset, duration, and frequency of exacerbations (see 108.00B7);

b. The prognosis of your skin disorder;

c. The location, size, and appearance of lesions and contractures;

d. Any available history of familial incidence;

e. Your exposure to toxins, allergens or irritants; seasonal variations; and stress factors;

f. Your ability to function outside of a highly protective environment (see 108.00E4);

g. Laboratory findings (for example, a biopsy obtained independently of Social Security disability evaluation or results of blood tests);

h. Evidence from other medically acceptable methods consistent with the prevailing state of medical knowledge and clinical practice; and

i. Statements you or others make about your disorder(s), your restrictions, and your daily activities.

D. *How do we evaluate the severity of skin disorders?*

1. *General.* We evaluate the severity of skin disorders based on the site(s) of your chronic skin lesions (see 108.00B2) or contractures (see 108.00B3), functional limitations caused by your signs and symptoms (including pain) (see 108.00D2), and how your prescribed treatment affects you. We consider the frequency and severity of your exacerbations (see 108.00B7), how quickly they resolve, and how you function between exacerbations (see 108.00B7), to determine whether your skin disorder meets or medically equals a listing (see 108.00D3). If there is no record of ongoing medical treatment for your disorder, we will follow the guidelines in 108.00D6. We will determine the extent and kinds of evidence we need from medical and non-medical sources based on the individual facts about your disorder. For our basic rules on evidence, see §§ 416.912, 416.913, and 416.920b of this chapter. For our rules on evaluating your symptoms, see § 416.929 of this chapter.

2. *Limitation(s) of physical functioning due to skin disorders.*

a. Skin disorders may be due to chronic skin lesions (see 108.00B2) or contractures (see 108.00B3), and may cause pain or restrict movement, which can limit your ability to initiate, sustain, and complete age-appropriate activities. For example, skin lesions in the axilla may limit your ability to raise or reach with the affected arm, or lesions in the inguinal region may limit your ability to ambulate, sit, or lift and carry. To evaluate your skin disorder(s) under 108.07B, 108.08, and 108.09, we require medically documented evidence of physical limitation(s) of functioning related to your disorder. The decrease in physical function must have lasted, or can be expected to last, for a continuous period of at least 12 months (see § 416.909 of this chapter). Xeroderma pigmentosum is the only skin disorder that does not include functional criteria because

the characteristics and severity of the disorder itself are sufficient to meet the criteria in 108.07A.

b. The functional criteria require impairment-related physical limitations in using upper or lower extremities that have lasted, or can be expected to last, for a continuous period of at least 12 months, medically documented by one of the following:

(i) Inability to use both upper extremities to the extent that neither can be used to independently initiate, sustain, and complete age-appropriate activities involving fine and gross movements (see 108.00B5) due to chronic skin lesions (see 108.00B2) or contractures (see 108.00B3); or

(ii) Inability to use one upper extremity to independently initiate, sustain, and complete age-appropriate activities involving fine and gross movements (see 108.00B5) due to chronic skin lesions (see 108.00B2) or contractures (see 108.00B3), and a documented medical need (see 108.00B4) for an assistive device (see 108.00B1) that requires the use of the other upper extremity; or

(iii) Inability to stand up from a seated position and maintain an upright position to the extent needed to independently initiate, sustain, and complete age-appropriate activities due to chronic skin lesions (see 108.00B2) or contractures (see 108.00B3) affecting at least two extremities (including when the limitations are due to involvement of the perineum or the inguinal region); or

(iv) Inability to maintain an upright position while standing or walking to the extent needed to independently initiate, sustain, and complete age-appropriate activities due to chronic skin lesions (see 108.00B2) or contractures (see 108.00B3) affecting both lower extremities (including when the limitations are due to involvement of the perineum or the inguinal region).

3. *Frequency of exacerbations due to chronic skin lesions.* A skin disorder resulting in chronic skin lesions (see 108.00B2) may have frequent exacerbations (see

108.00B7) severe enough to meet a listing even if each individual skin lesion exacerbation (see 108.00B7) did not last for an extended amount of time. We will consider the frequency, severity, and duration of skin lesion exacerbations (see 108.00B7), how quickly they resolve, and how you function in the time between skin lesion exacerbations (see 108.00B7), to determine whether your skin disorder meets or medically equals a listing.

4. *Symptoms (including pain).* Your symptoms may be an important factor in our determination of whether your skin disorder(s) meets or medically equals a listing. We consider your symptoms only when you have a medically determinable impairment(s) that could reasonably be expected to produce the symptoms. See § 416.929 of this chapter.

5. *Treatment.*

a. *General.* Treatments for skin disorders may have beneficial or adverse effects, and responses to treatment vary from person to person. Your skin disorder's response to treatment may vary due to treatment resistance or side effects that can result in functional limitations. We will evaluate all of the effects of treatment (including surgical treatment, medications, and therapy) on the symptoms, signs, and laboratory findings of your skin disorder, and on your ability to function.

b. *Despite adherence to prescribed medical treatment for 3 months.* Under 108.09, we require that your symptoms persist "despite adherence to prescribed medical treatment for 3 months." This requirement means that you must have taken prescribed medication(s) or followed other medical treatment prescribed by a medical source for 3 consecutive months. Treatment or effects of treatment may be temporary. In most cases, sufficient time must elapse to allow us to evaluate your response to treatment, including any side effects. For our purposes, "sufficient time" means a period of at least 3 months. If your treatment has not lasted for at least 3 months, we will follow the rules in

108.00D6a. The 3 months adherence to prescribed medical treatment must be within the period of at least 12 months that we use to evaluate severity.

c. *Treatment with PUVA (psoralen and ultraviolet A (UVA) light) or biologics.* If you receive additional treatment with PUVA or biologics to treat your skin disorder(s), we will defer adjudication of your claim for 6 months from the start of treatment with PUVA or biologics to evaluate the effectiveness of these treatments unless we can make a fully favorable determination or decision on another basis.

6. *No record of ongoing treatment.*

a. Despite having a skin disorder, you may not have received ongoing treatment, may have just begun treatment, may not have access to prescribed medical treatment, or may not have an ongoing relationship with the medical community. In any of these situations, you will not have a longitudinal medical record for us to review when we evaluate your disorder. In some instances, we may be able to assess the severity and duration of your skin disorder based on your medical record and current evidence alone. We may ask you to attend a consultative examination to determine the severity and potential duration of your skin disorder (see § 416.919a of this chapter).

b. If, for any reason, you have not received treatment, your skin disorder cannot meet the criteria for 108.09. If the information in your case record is not sufficient to show that you have a skin disorder that meets the criteria of one of the skin disorders listings, we will follow the rules in 108.00I.

E. *How do we evaluate genetic photosensitivity disorders under 108.07?* Genetic photosensitivity disorders are disorders of the skin caused by an increase in the sensitivity of the skin to sources of ultraviolet light, including sunlight.

1. *Xeroderma pigmentosum (XP) (108.07A).* XP is a genetic photosensitivity disorder with lifelong hypersensitivity to all forms of ultraviolet light. Laboratory testing confirms the diagnosis by documenting abnormalities in the body’s ability to repair DNA

(deoxyribonucleic acid) mutations after ultraviolet light exposure. Your skin disorder meets the requirements of 108.07A if you have clinical and laboratory findings supporting a diagnosis of XP (see 108.00E3).

2. *Other genetic photosensitivity disorders (108.07B).* The effects of other genetic photosensitivity disorders may vary and may not persist over time. To meet the requirements of 108.07B, a genetic photosensitivity disorder other than XP must be established by clinical and laboratory findings (see 108.00C) and must result either in chronic skin lesions (see 108.00B2) or contractures (see 108.00B3) that result in functional limitations (108.00D2), or must result in the inability to function outside of a highly protective environment (see 108.00E4). Some genetic photosensitivity disorders can have very serious effects on other body systems, especially special senses and speech, neurological, mental, and cancer. We will evaluate your disorder(s) under the listings in 102.00, 111.00, 112.00, or 113.00, as appropriate.

3. *What evidence do we need to document that you have XP or another genetic photosensitivity disorder?* We will make a reasonable effort to obtain evidence of your disorder(s), but we will not purchase genetic testing. When the results of genetic tests are part of the existing evidence in your case record, we will evaluate the test results with all other relevant evidence. We need the following clinical and laboratory findings to document that you have XP or another genetic photosensitivity disorder:

a. A laboratory report of a definitive genetic test documenting appropriate chromosomal changes, including abnormal DNA repair or another DNA abnormality specific to your type of photosensitivity disorder, signed by an AMS; or

b. A laboratory report of a definitive test that is not signed by an AMS, and a report from an AMS stating that you have undergone definitive genetic laboratory studies documenting appropriate chromosomal changes, including abnormal DNA repair or another DNA abnormality specific to your type of photosensitivity disorder; or

c. If we do not have a laboratory report of a definitive test, we need documentation from an AMS that an appropriate laboratory analysis or other diagnostic method(s) confirms a positive diagnosis of your skin disorder. This documentation must state that you had the appropriate definitive laboratory test(s) for diagnosing your disorder and provide the results, or explain how another diagnostic method(s), consistent with the prevailing state of medical knowledge and clinical practice, established your diagnosis.

4. *Inability to function outside of a highly protective environment* means that you must avoid exposure to ultraviolet light (including sunlight passing through windows and light from similar unshielded light sources), wear protective clothing and eyeglasses, and use opaque broad-spectrum sunscreens in order to avoid skin cancer or other serious effects.

F. *How do we evaluate burns under 108.08?*

1. Electrical, chemical, or thermal burns frequently affect other body systems; for example, musculoskeletal, special senses and speech, respiratory, cardiovascular, genitourinary, neurological, or mental. We evaluate burns in the same way we evaluate other disorders that can affect the skin and other body systems, using the listing for the predominant feature of your disorder. For example, if your soft tissue injuries resulting from burns are under surgical management (as defined in 108.00B6), we will evaluate your disorder under the listings in 101.00.

2. We evaluate burns resulting in chronic skin lesions (see 108.00B2) or contractures (see 108.00B3) that have been documented by an AMS to have reached maximum therapeutic benefit and therefore are no longer receiving surgical management, under 108.08. To be disabling, these burns must result in functional limitation(s) (see 108.00D2) that has lasted or can be expected to last for a continuous period of at least 12 months.

G. *How do we evaluate chronic conditions of the skin or mucous membranes under 108.09?* We evaluate skin disorders that result in chronic skin lesions (see 108.00B2) or contractures (see 108.00B3) under 108.09. These disorders must result in chronic skin lesions (see 108.00B2) or contractures (see 108.00B3) that continue to persist despite adherence to prescribed medical treatment for 3 months (see 108.00D5b) and cause functional limitations (see 108.00D2). Examples of skin disorders evaluated under this listing are ichthyosis, bullous diseases (such as pemphigus, epidermolysis bullosa, and dermatitis herpetiformis), chronic skin infections, dermatitis, psoriasis, and hidradenitis suppurativa.

H. *How do we evaluate disorders in other body systems that affect the skin?* When your disorder(s) in another body system affects your skin, we first evaluate the predominant feature of your disorder(s) under the appropriate body system. Examples of disorders in other body systems that affect the skin include the following:

1. *Tuberous sclerosis.* The predominant functionally limiting features of tuberous sclerosis are seizures and intellectual disorder or other mental disorders. We evaluate these features under the listings in 111.00 or 112.00, as appropriate.

2. *Malignant tumors of the skin.* Malignant tumors of the skin (for example, malignant melanomas) are cancers, or malignant neoplastic diseases, that we evaluate under the listings in 113.00.

3. *Immune system disorders.* We evaluate skin manifestations of immune system disorders such as systemic lupus erythematosus, scleroderma, psoriasis, and human immunodeficiency virus (HIV) infection under the listings in 114.00.

4. *Head or facial disfigurement or deformity, and other physical deformities caused by skin disorders.* A head or facial disfigurement or deformity may result in loss of your sight, hearing, speech, or ability to chew. In addition to head and facial disfigurement and deformity, other physical deformities may result in associated

psychological problems (for example, depression). We evaluate the effects of head or facial disfigurement or deformity, or other physical deformities caused by skin disorders under the listings in 101.00, 102.00, 105.00, or 112.00, as appropriate.

5. *Porphyria.* We evaluate erythropoietic protoporphyria under the listings in 107.00.

6. *Hemangiomas.* We evaluate hemangiomas associated with thrombocytopenia and hemorrhage (for example, Kasabach-Merritt syndrome) involving coagulation defects under the listings in 107.00. When hemangiomas impinge on vital structures or interfere with functioning, we evaluate their primary effects under the listings in the appropriate body system.

I. *How do we evaluate skin disorders that do not meet one of these listings?*

1. These listings are only examples of common skin disorders that we consider severe enough to result in marked and severe limitations. If your impairment(s) does not meet the criteria of any of these listings, we must also consider whether you have an impairment(s) that satisfies the criteria of a listing in another body system.

2. If you have a severe medically determinable impairment(s) that does not meet a listing, we will determine whether your impairment(s) medically equals a listing. See § 416.926 of this chapter. If your impairment(s) does not meet or medically equal a listing, we will also consider whether your impairment(s) functionally equals the listings. See § 416.926a of this chapter. We use the rules in § 416.994a of this chapter when we decide whether you continue to be disabled.

108.01 Category of Impairments, Skin Disorders

108.02–108.06 [Reserved]

108.07 *Genetic photosensitivity disorders*, established as described in 108.00E. The requirements of this listing are met if either paragraph A or paragraph B is satisfied.

A. Xeroderma pigmentosum (see 108.00E1).

OR

B. Other genetic photosensitivity disorders (see 108.00E2) with either 1 or 2:

1. Chronic skin lesions (see 108.00B2) or contractures (see 108.00B3) that cause an inability to function outside of a highly protective environment (see 108.00E4); or

2. Chronic skin lesions (see 108.00B2) or contractures (see 108.00B3) causing chronic pain or other physical limitation(s) that result in impairment-related functional limitations (see 108.00D2), as evidenced by:

a. Inability to use both upper extremities to the extent that neither can be used to independently initiate, sustain, and complete age-appropriate activities involving fine and gross movements (see 108.00B5) due to chronic skin lesions (see 108.00B2) or contractures (see 108.00B3); or

b. Inability to use one upper extremity to independently initiate, sustain, and complete age-appropriate activities involving fine and gross movements (see 108.00B5) due to chronic skin lesions (see 108.00B2) or contractures (see 108.00B3), and a documented medical need (see 108.00B4) for an assistive device (see 108.00B1) that requires the use of the other upper extremity; or

c. Inability to stand up from a seated position and maintain an upright position to the extent needed to independently initiate, sustain, and complete age-appropriate activities due to chronic skin lesions (see 108.00B2) or contractures (see 108.00B3) affecting at least two extremities (including when the limitations are due to involvement of the perineum or the inguinal region); or

d. Inability to maintain an upright position while standing or walking to the extent needed to independently initiate, sustain, and complete age-appropriate activities due to chronic skin lesions (see 108.00B2) or contractures (see 108.00B3) affecting both lower extremities (including when the limitations are due to involvement of the perineum or the inguinal region).

108.08 *Burns* (see 108.00F). Burns that do not require continuing surgical management (see 108.00B6), or that have been documented by an acceptable medical source to have reached maximum therapeutic benefit and are no longer receiving surgical management, resulting in chronic skin lesions (see 108.00B2) or contractures (see 108.00B3) causing chronic pain or other physical limitation(s) that result in impairment-related functional limitations (see 108.00D2), as evidenced by:

A. Inability to use both upper extremities to the extent that neither can be used to independently initiate, sustain, and complete age-appropriate activities involving fine and gross movements (see 108.00B5) due to chronic skin lesions (see 108.00B2) or contractures (see 108.00B3).

OR

B. Inability to use one upper extremity to independently initiate, sustain, and complete age-appropriate activities involving fine and gross movements (see 108.00B5) due to chronic skin lesions (see 108.00B2) or contractures (see 108.00B3), and a documented medical need (see 108.00B4) for an assistive device (see 108.00B1) that requires the use of the other upper extremity.

OR

C. Inability to stand up from a seated position and maintain an upright position to the extent needed to independently initiate, sustain, and complete age-appropriate activities due to chronic skin lesions (see 108.00B2) or contractures (see 108.00B3) affecting at least two extremities (including when the limitations are due to involvement of the perineum or the inguinal region).

OR

D. Inability to maintain an upright position while standing or walking to the extent needed to independently initiate, sustain, and complete age-appropriate activities due to chronic skin lesions (see 108.00B2) or contractures (see 108.00B3) affecting both

lower extremities (including when the limitations are due to involvement of the perineum or the inguinal region).

108.09 *Chronic conditions of the skin or mucous membranes* (see 108.00G) resulting in:

A. Chronic skin lesions (see 108.00B2) or contractures (see 108.00B3) causing chronic pain or other physical limitation(s) that persist despite adherence to prescribed medical treatment for 3 months (see 108.00D5b).

AND

B. Impairment-related functional limitations (see 108.00D2) demonstrated by 1, 2, 3, or 4:

1. Inability to use both upper extremities to the extent that neither can be used to independently initiate, sustain, and complete age-appropriate activities involving fine and gross movements (see 108.00B5) due to chronic skin lesions (see 108.00B2) or contractures (see 108.00B3); or

2. Inability to use one upper extremity to independently initiate, sustain, and complete age-appropriate activities involving fine and gross movements (see 108.00B5) due to chronic skin lesions (see 108.00B2) or contractures (see 108.00B3), and a documented medical need (see 108.00B4) for an assistive device (see 108.00B1) that requires the use of the other upper extremity; or

3. Inability to stand up from a seated position and maintain an upright position to the extent needed to independently initiate, sustain, and complete age-appropriate activities due to chronic skin lesions (see 108.00B2) or contractures (see 108.00B3) affecting at least two extremities (including when the limitations are due to involvement of the perineum or the inguinal region); or

4. Inability to maintain an upright position while standing or walking to the extent needed to independently initiate, sustain, and complete age-appropriate activities due to

chronic skin lesions (see 108.00B2) or contractures (see 108.00B3) affecting both lower extremities (including when the limitations are due to involvement of the perineum or the inguinal region).

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114.00 Immune System Disorders

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F. * * *

7. * * *

b. * * *

(iii) BMI is the ratio of a child's weight to the square of his or her height. We calculate BMI using the formulas in the digestive disorders body system (105.00).

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